IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| NOVO NORDISK A/S,<br><br>Plaintiff,<br><br>v.<br><br>SANOFI-AVENTIS, AVENTIS PHARMACEUTICALS INC., and AVENTIS PHARMA DEUTSCHLAND GMBH,<br><br>Defendants. | ) | C.A. No. 05-645-SLR<br><br>**REDACTED PUBLIC VERSION** |

**AVENTIS'S RESPONSE TO NOVO NORDISK A/S'S MOTION TO VOLUNTARILY DISMISS THE COMPLAINT AND TO DISMISS DEFENDANTS' COUNTERCLAIMS FOR LACK OF SUBJECT MATTER JURISDICTION**

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Dated: July 19, 2007
182441.1

## I. INTRODUCTION

Aventis Pharmaceuticals Inc., sanofi-aventis, and sanofi-aventis Deutschland GmbH[1] (collectively "Aventis") hereby respond to Novo Nordisk A/S's Motion to Voluntarily Dismiss the Complaint and to Dismiss Defendants' Counterclaims for Lack of Subject Matter Jurisdiction (D.I. 152) ("Motion to Dismiss").

While Aventis does not oppose the dismissal of Novo's lawsuit, Aventis objects to the dismissal order proposed by Novo and to Novo's covenant not to sue. First, Novo's infringement claims should be dismissed with prejudice. Novo's attempt to secure a dismissal without prejudice (which would allow Novo to re-file this suit) is squarely at odds with its covenant not to sue (which would prevent Novo from re-filing this suit). Furthermore, the eleventh-hour filing of the Motion to Dismiss—shortly before the pretrial conference, and only after Aventis was forced to go to the expense of essentially completing fact and expert discovery and preparing for trial—more than justifies dismissal with prejudice. Indeed, Novo's attempt to have this action dismissed without prejudice seems calculated to preclude Aventis from recovering costs or seeking attorney fees as a prevailing party. Aventis maintains, however, that Novo brought and prosecuted this action—based on an unenforceable patent—in bad faith. Accordingly, Aventis requests that the Court exercise its discretion under Fed. R. Civ. P. 41(a)(2) to dismiss Novo's infringement claims with prejudice (to truly remove any apprehension of suit), and to declare Aventis the prevailing party for the purposes of recovering taxable costs pursuant to Fed. R. Civ. P. 54(d) and for the purposes of seeking attorney fees pursuant to 35 U.S.C. § 285.

[1] Although the Complaint names Aventis Pharma Deutschland GmbH, this entity is now known as sanofi-aventis Deutschland GmbH, and the dismissal of this case should be inclusive of both entities.

## II. ARGUMENT

### A. Novo's Claims Should Be Dismissed with Prejudice

Novo's Motion to Dismiss is governed by Fed. R. Civ. P. 41(a)(2), which gives the Court discretion to determine the terms and conditions upon which Novo's dismissal may be granted. Pursuant to Fed. R. Civ. P. 41(a)(2), "an action shall not be dismissed at the plaintiff's instance save upon order of the court and upon such terms and conditions as the court deems proper. . . . Unless otherwise specified in the order, a dismissal under this paragraph is without prejudice." Fed. R. Civ. P. 41(a)(2). When a plaintiff moves for dismissal pursuant to Fed. R. Civ. P. 41(a)(2), the decision to dismiss with or without prejudice is left to the discretion of the district court. *Mobil Oil Corp. v. Advanced Envtl. Recycling Techs., Inc.*, 203 F.R.D. 156, 157 (D. Del. 2001). In considering whether to enter a dismissal with prejudice, courts in this jurisdiction consider several factors, including the extent of discovery conducted in the matter. *Id.* at 158. Additional factors that the Court may consider include: "(1) the defendants' efforts and expense in preparing for trial; (2) excessive delay and lack of diligence on the part of the movant; (3) insufficient explanation of the need for voluntary dismissal; and (4) excessive and duplicative expense of a second litigation." *Barrett v. Vesuvius McDanel*, No. 06-994, 2007 WL 1670121, at *3 (W.D. Pa. June 8, 2007); *see also Reach & Assocs., P.C. v. Dencer*, No. 02-1355 JJF, 2004 WL 253487, at *1 (D. Del. Feb. 9, 2004). Consideration of these factors in this case supports dismissal of Novo's complaint with prejudice.

Contrary to Novo's representations, the fact that Novo has submitted a covenant not to sue does not deprive this Court of its ability to exercise discretion in dismissing this action. Indeed, the Federal Circuit has recently explained that while a covenant not to sue may eliminate the case or controversy with respect to patent-related counterclaims, "the covenant does not deprive the district court of jurisdiction to determine the disposition of the patent infringement claims raised in the

Complaint under Rule 41 or the request for attorney fees under 35 U.S.C. § 285." *Highway Equip. Co. v. FECO, Ltd.*, 469 F.3d 1027, 1033 n.1 (Fed. Cir. 2006).

**1. Aventis's Extensive Preparation for Trial Justifies Dismissal with Prejudice**

Novo's Motion to Dismiss was filed less than one month before the final pre-trial conference in this case, scheduled for July 31, 2007, and comes barely a month before the first scheduled day of trial itself, August 13, 2007. At this point, fact discovery is essentially complete[2], and expert discovery is entirely completed. Thus, discovery in this case has run its course, leaving trial as the only remaining substantive matter to be completed.

Aventis's efforts in preparing for trial have been extensive and include at least the following:

- the collection and production of nearly seven hundred thousand pages of documents[3];
- taking and defending 25 depositions, a majority of which took place in Europe;
- extensive translation of foreign language documents;
- expert discovery, including preparation of expert reports on noninfringement, invalidity and damages, as well as expert depositions; and
- preparation for trial, including preparation of trial exhibits, witnesses, and a pre-trial order.

REDACTED To allow dismissal ***without*** prejudice at this advanced stage in the litigation—following the effort and expense incurred by Aventis—would be inequitable. *See, e.g., Reach & Assocs., P.C.*, 2004 WL 253487, at *1; *Deuterium Corp. v. United States*, 21 Cl. Ct. 132, 135-36 (Cl. Ct. 1990) ("[D]ismissal with prejudice is appropriate because of the enormous amount of time and money defendant has spent in preparation for trial . . . which is scheduled to begin in less than two months.") (opinion

[2] Two scheduled depositions remain to be taken, and these would have been completed on July 17-18, 2007, had Novo not canceled the depositions. Ex. A.
[3] In contrast, Novo has produced fewer than 60,000 pages of documents.

attached at Exhibit B). Accordingly, the belated timing of Novo's motion strongly supports dismissal with prejudice.

**2. Novo's Unnecessary Delay in Filing Its Motion to Dismiss Justifies Dismissal with Prejudice**

There is no valid excuse for Novo filing its Motion to Dismiss so close to trial. Novo's motion is based on old information, and if it wanted to dismiss this case, Novo should have and could have done so long ago. For example, Novo relies upon several Ypsomed press releases to support its allegations that the OptiClik® device "has been beset by difficulties," but these press releases were issued in 2006. Motion to Dismiss at 3; Vitola Decl. Exs. 1-3. Undoubtedly, Novo knew of these press releases months ago. In addition, in attempting to explain the purported basis for its Motion to Dismiss, Novo used many of the same arguments that it made when dismissing its International Trade Commission ("ITC") action against Aventis in October 2006. Motion to Dismiss at 3; Ex. C at 2, 7-8.

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None of these purported bases occurred recently.

Even though Novo knew all of this information—the backbone of Novo's "justification" for dismissal—almost five months ago, Novo has allowed Aventis to continue its diligent and expensive trial preparations. In light of Novo's unjustified delay, the only equitable resolution of this lawsuit is dismissal of Novo's claims with prejudice.

**3. Novo's Insufficient Explanation of Its Need for Dismissal Justifies Dismissal with Prejudice**

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REDACTED

**4. A Second Lawsuit Will Needlessly Duplicate the Parties' Expenses, Thereby Justifying Dismissal with Prejudice**

If Novo's claims are dismissed without prejudice, Aventis faces the prospect of a second lawsuit, especially if, in the future, Novo should judge the sales of the OptiClik® device to be sufficient to justify such a suit. Aventis is ready for trial now. If the trial is postponed indefinitely, much of Aventis's preparation for trial will have to be re-done, at considerable expense. Additionally, witnesses' memories will fade and witnesses may become more inaccessible, potentially precluding Aventis from eliciting their testimony.

REDACTED

The risk of such problems will only increase by postponing resolution to a future trial.

**5. Dismissal with Prejudice Is Consistent with Novo's Covenant Not to Sue**

Finally, dismissal without prejudice is inconsistent with Novo's covenant not to sue. Novo's argument that its covenant not to sue will protect Aventis from a future lawsuit against the OptiClik® device under the '408 patent cannot be squared with Novo's attempt to seek a dismissal that preserves the right to re-file its claims. Because Novo is seeking to dismiss this case through a covenant not to sue, the case should be dismissed with prejudice. While Novo will suffer no harm as a result of a dismissal with prejudice, a dismissal without prejudice may deprive Aventis of the opportunity to seek costs or attorney fees. Thus, the equities favor a dismissal with prejudice.

**B. Aventis Should Be Declared the Prevailing Party**

Aventis requests that it be declared the prevailing party in this action, to clarify that Aventis may recover its costs pursuant to Fed. R. Civ. P. 54(d)(1). Likewise, Aventis wishes to file a motion to recover its attorney fees pursuant to Fed. R. Civ. P. 54(d)(2) and 35 U.S.C. § 285. *Callaway Golf Co. v. Slazenger*, 384 F. Supp. 2d 735, 746 (D. Del. 2005); *see also Dekalb Genetics Corp. v. Pioneer Hi-Bred Int'l*, No. 96C50113, 2002 WL 1308651, at *1 (N.D. Ill. June 13, 2002) (citing Appeal Court decisions in accord with proposition that voluntary dismissal with prejudice confers prevailing party status).

Aventis believes that at least two independent bases exist for finding this case to be exceptional under 35 U.S.C. § 285—inequitable conduct and bad faith litigation. For example, Aventis believes Novo's patent is invalid over Novo's own prior art devices/publications, as well as over references known to Novo from the prosecution of a related patent, all of which Novo withheld from the Patent Office.

Aventis also asserts that Novo has engaged in a pattern of bad faith litigation. Significantly, this is the second time in recent history that Novo has belatedly voluntarily dismissed an action against Aventis. On May 8, 2006, Novo filed an action against Aventis before the ITC, alleging that the very same OptiClik® device as in this case infringed yet another Novo patent. As in the present case, Novo also refused to produce evidence of its own prior art syringe devices in response to Aventis' requests for discovery. Because of Novo's refusal to produce relevant evidence, Aventis was forced to spend over $1 million to obtain information about Novo's prior art syringe devices from third parties—information which showed that the patent at issue in the ITC action was invalid and unenforceable. In response to Aventis' attempts to compel Novo to produce Novo's own prior art documents, Novo chose to withdraw its ITC complaint rather than attempt to justify its conduct in

withholding the relevant information. In both the ITC litigation and the instant case, Novo belatedly dismissed its claims despite knowing early on that there was no merit to its positions.[5] Accordingly, Aventis respectfully requests that this Court enter an order (in the form attached) to preserve its right to seek attorney fees for Novo's actions.

**C. Novo's Covenant Not to Sue Is Too Narrow**

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[5] Following this pattern, within one week of filing this motion, and with no prior notice to Aventis, Novo again filed suit against Aventis's new insulin injector device in New Jersey District Court (Case 3:07-cv-03206-MLC-JJH, filed on July 10, 2007).

## III. CONCLUSION

For the foregoing reasons, Aventis respectfully requests the Court to enter Aventis's proposed order (filed herewith) dismissing Novo's claims with prejudice, declaring Aventis the prevailing party, and setting a schedule for briefing costs and attorney fees.

ASHBY & GEDDES

/s/ *John G. Day*

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Dated: July 19, 2007
182441.1

# Exhibit A

mbhb McDonnell Boehnen Hulbert & Berghoff LLP

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July 6, 2007

***VIA FACSIMILE***
***212 354 8113***

Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036-2787

Re: ***Novo Nordisk A/S v. sanofi-aventis et al.***
***Civil Action No. 05-00645 SLR***

Dear Steve:

We write to confirm your conversation with Mr. McCarthy on July 5. Regarding the depositions of Daniel Gruber and Hermann Koch, you informed us that Novo is not going to take either deposition. Regarding the pre-trial order, you informed us that Novo will not, in light of Novo's motion to dismiss, proceed with the preparation of the pre-trial order and that Novo will not provide a draft pre-trial order for Aventis's review.

Regards,

Eric R. Moran
312 913 3302 direct
moran@mbhb.com

# Confirmation Report–Memory Send

Time : Jul-06-07 02:45pm
Tel line 1 : +131291300002
Name : MCDONNELL BOEHNEN HULBERT & BERGHOFF

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Job number : 895 *** SEND SUCCESSFUL ***

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McDonnell Boehnen Hulbert & Berghoff LLP

## Fax transmittal

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|---|---|---|---|
| To | Stephen J. Vitola | Date | July 6, 2007 |
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| | 212 819 7800 | Email | moran@mbhb.com |
| Phone | | C/M | 690/28 |
| Copy To | | | |
| Pages, with cover | 2 | | |
| Re | ***Novo Nordisk A/S v. sanofi-aventis et al.*** ***Civil Action No. 05-00645 SLR*** | | |

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# Exhibit B

H

Deuterium Corp. v. U.S.
Cl.Ct.,1990.

United States Claims Court.
DEUTERIUM CORPORATION, Plaintiff,
v.
The UNITED STATES, Defendant,
v.
EIC LABORATORIES, INC., Third-Party Defendant.
**No. 425-82 C.**

Aug. 14, 1990.

Corporation brought action alleging patent infringement, Fifth Amendment taking, and breaches of implied and express contracts. After summary judgment was granted on patent infringement count, corporation moved to voluntarily withdraw all other counts of complaint and requested to proceed in forma pauperis in appealing dismissal. The Claims Court, Rader, J., held that: (1) requested dismissal would be with prejudice, and (2) only natural persons, not corporations, were entitled to proceed in forma pauperis.

Ordered accordingly.

West Headnotes

**[1] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

In granting voluntary dismissal request under Claims Court rule, court has considerable latitude and discretion and may set conditions on dismissal that it deems proper. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[2] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Dismissal without prejudice is norm, rather than exception, on voluntary dismissal request under Claims Court rule, but court can still exercise considerable discretion by offering reasonable grounds when dismissing action with prejudice. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[3] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

No precise formula governs when dismissals voluntarily requested under Claims Court rule will be with prejudice. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[4] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Decision on when dismissals voluntarily requested under Claims Court rule will be with prejudice largely hinges on equities of case, with due regard for interests of both parties. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[5] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Grounds for dismissing with prejudice upon voluntary dismissal request under Claims Court rule generally fall into three broad categories: burden on defendant of dismissal without prejudice, progress of litigation, and diligence and good faith of plaintiff. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[6] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

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**(Cite as: 21 Cl.Ct. 132)**

Dismissal with prejudice upon voluntary dismissal request under Claims Court rule is particularly appropriate where plaintiff moves to withdraw during pendency of summary judgment motion filed by defendant. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[7] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Dismissal with prejudice was appropriate on voluntary dismissal request under Claims Court rule, where litigation had been pending for eight years, extensive discovery had been conducted, motion to withdraw came on eve of scheduled ten-day trial, and plaintiff asserted need to withdraw because of lack of financial resources only after eight years of aggressive litigation, although plaintiff must have known for years, after it became an insolvent shell corporation, that it faced financial instability. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[8] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Dismissal with prejudice upon voluntary dismissal request under Claims Court rule is appropriate where there have been extensive proceedings with trial clearly in sight. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[9] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

If plaintiff has not prosecuted his case with diligence and good faith, it is appropriate for court to grant voluntary motion to withdraw with prejudice. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[10] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Insufficient explanation of need for dismissal, using dismissal to deprive defendant of ruling on dispositive motion, and excessive delay are among factors which justify dismissal with prejudice upon voluntary request for dismissal. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[11] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Court should dismiss with prejudice upon voluntary request for dismissal if the request merely represents attempt to relitigate under more favorable circumstances. U.S.Cl.Ct.Rule 41, 28 U.S.C.A.

**[12] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases

Statute permitting court to authorize suit without prepayment of fees and costs contemplates that natural person, not corporation, is entitled to proceed in forma pauperis, and form of required affidavits similarly envisions that only natural persons will make such a request. 28 U.S.C.A. § 1915(a); F.R.A.P.Rule 24, 28 U.S.C.A.

**[13] Federal Courts 170B 663**

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(E) Proceedings for Transfer of Case
170Bk662 Proceedings in Forma Pauperis
170Bk663 k. Grounds for Permitting or Refusing. Most Cited Cases

**Federal Courts 170B 664**

170B Federal Courts
170BVIII Courts of Appeals
170BVIII(E) Proceedings for Transfer of Case
170Bk662 Proceedings in Forma Pauperis
170Bk664 k. Affidavits and Proceedings. Most Cited Cases

Plaintiff corporation would not be permitted to

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proceed in forma pauperis on appeal; statute and form of required affidavit indicate that only natural persons are entitled to proceed in forma pauperis, corporation had not filed affidavit in accordance with required form, and plaintiff corporation had had sufficient resources to sue vigorously for eight years, but pled financial distress on eve of trial without any apparent change in its finances. 28 U.S.C.A. § 1915(a); F.R.A.P.Rule 24, 28 U.S.C.A.

**[14] Federal Courts 170B 1101**

170B Federal Courts
170BXII Claims Court (Formerly Court of Claims)
170BXII(B) Procedure
170Bk1101 k. Procedure in General. Most Cited Cases
Party need not succeed on the merits to escape harshness of Rule 11 sanctions. U.S.Cl.Ct.Rule 11, 28 U.S.C.A.

**Patents 291 328(2)**

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original Utility. Most Cited Cases
4,123,506. Cited.

***133** David M. Singer, Greenwich, Conn., for plaintiff.
Oscar A. Towler, III, Washington, D.C., Asst. Atty. Gen. Stuart M. Gerson, for defendant.
Charles C. Winchester, Boston, Mass., for third-party defendant.

OPINION

RADER, Judge.

On July 24, 1990, plaintiff, Deuterium Corporation, filed a motion to withdraw voluntarily all counts of its complaint not already dismissed by this court. RUSCC 41(a)(2). Plaintiff also requested to proceed *in forma pauperis* in appealing this court's prior dismissal of two counts of the complaint. Fed.R.App. P. 24. Defendant has opposed plaintiff's motion as well as the request to proceed *in forma pauperis.* Moreover, defendant has asked this court to impose sanctions against plaintiff pursuant to RUSCC 11.

After reviewing the thorough written submissions of both parties, this court grants with prejudice plaintiff's motion to withdraw and denies plaintiff's request to proceed *in forma pauperis* on appeal. The court also denies defendant's request for Rule 11 sanctions.

BACKGROUND

On August 26, 1982, plaintiff instituted this action against the United States and EIC Laboratories, Inc. Approximately one year later, plaintiff amended its complaint to include several other counts. The complaint as amended contains four principal counts. In Count One, plaintiff alleged infringement of United States Patent No. 4,123,506 (the '506 patent). In Count Two, plaintiff alleged a fifth amendment taking. In Count Three and Count Four, plaintiff alleged breaches of implied and express contracts.[FN1]

FN1. All other aspects of plaintiff's complaint involve issues that are subsidiary to these four principal counts.

In Count One-the patent infringement count-plaintiff alleged two unauthorized uses. First, plaintiff contended that the Government infringed the '506 patent while generating electricity with purified steam ***134** during a 120-hour test period in 1978. Second, plaintiff asserted that Pacific Gas and Electric (PG & E), EIC's subcontractor, infringed the patent by using steam to heat liquid reactants inside a pilot plant. This court has rejected both of plaintiff's infringement allegations by granting defendant summary judgment on two separate occasions. *Deuterium Corp. v. United States,* 19 Cl.Ct. 624 (1990); *Deuterium Corp. v. United States,* 16 Cl.Ct. 454 (1989).[FN2] In a telephone status conference held by this court on July 12, 1990, both parties acknowledged that the court's two decisions dispose entirely of Count One.

FN2. This court has denied motions by plaintiff to reconsider both opinions, Opinion, No. 425-82 C, filed July 14, 1989 (unpublished); Opinion, No. 425-82 C, filed July 9, 1990 (unpublished).

On July 24, 1990, plaintiff moved to withdraw its remaining counts.[FN3] Plaintiff also asked to proceed *in forma pauperis* on appeal of the Count One dismissal. In support of its motion, plaintiff claims that it has insufficient funds to pursue the litigation properly.

FN3. In the alternative, plaintiff seeks to amend its complaint pursuant to RUSCC 15 by striking references to the counts not yet

21 Cl.Ct. 132



dismissed by this court.

Defendant opposes plaintiff's motion. Defendant seeks instead dismissal with prejudice. Defendant fears prejudice to the Government if this court dismisses without prejudice and plaintiff later refiles. Plaintiff has represented, however, that it will not litigate further unless an appeal, if taken, reverses this court's judgment on Count One.

DISCUSSION

*Motion to Withdraw*

RUSCC 41 authorizes this court to dismiss a complaint upon plaintiff's voluntary request. In pertinent part, Rule 41 provides:
[A]n action shall not be dismissed at the plaintiff's instance save upon order of the court and upon such terms and conditions as the court deems proper.... Unless otherwise specified in the order, a dismissal under this paragraph is without prejudice.

RUSCC 41(a)(2).

[1][2] The language of Rule 41 makes two points about the court's role in granting voluntary dismissal. First, the court has considerable latitude and discretion. The court may set conditions on dismissal " as it deems proper." Second, dismissal without prejudice is the norm rather than the exception. A court can respect this norm and still exercise considerable discretion by offering reasonable grounds when dismissing an action with prejudice. *See, e.g.*, *Link v. Wabash R.R. Co.*, 370 U.S. 626, 629-33, 82 S.Ct. 1386, 1388-90, 8 L.Ed.2d 734 (1962); *Durham v. Florida East Coast Ry. Co.*, 385 F.2d 366, 367-68 (5th Cir.1967).

[3][4][5] No precise formula governs dismissals with prejudice. The decision largely hinges on the equities of the case, with due regard for the interests of both parties. *Cone v. West Virginia Pulp & Paper Co.*, 330 U.S. 212, 67 S.Ct. 752, 91 L.Ed. 849 (1947); *Le Compte v. Mr. Chip, Inc.*, 528 F.2d 601 (5th Cir.1976). The grounds for dismissing with prejudice, however, fall generally into three broad categories: the burden on defendant of dismissal without prejudice, the progress of the litigation, and the diligence and good faith of the plaintiff.

*Burden on Defendant*

[6] Federal courts often grant a motion to withdraw with prejudice where defendant has incurred great time and expense in preparing for trial. *Alumni Ass'n of Univ. of North Carolina, Inc. v. United States*, 650 F.2d 287, 223 Ct.Cl. 765 (1980); *Andes v. Versant Corp.*, 788 F.2d 1033 (4th Cir.1986); *Ferguson v. Eakle*, 492 F.2d 26 (3rd Cir.1974); *Pace v. Southern Express Co.*, 409 F.2d 331 (7th Cir.1969); *see also*, *Thomas v. Amerada Hess Corp.*, 393 F.Supp. 58 (M.D.Pa.1975); *Selas Corp. of America v. Wilshire Oil Co.*, 57 F.R.D. 3 (E.D.Pa.1972). Dismissal with prejudice is particularly appropriate where plaintiff moves to withdraw during the pendency of a summary judgment motion filed by defendant.***135** *See* *Pace*, 409 F.2d 331; *Thomas*, 393 F.Supp. 58; *Woolgar v. La Coste*, 69 F.Supp. 571 (W.D.La.1947); *Love v. Silas Mason Co.*, 66 F.Supp. 753 (W.D.La.1946).

[7] Here, dismissal with prejudice is appropriate because of the enormous amount of time and money defendant has spent in preparation for trial. Defendant already has conducted extensive discovery for a trial which is scheduled to begin in less than two months. In 1983, defendant engaged in the production of documents and fought an extensive battle over protective orders for certain evidence. In 1984, defendant complied with plaintiff's interrogatory and other discovery requests. Defendant also engaged in another heated discovery battle over the privileged nature of certain requested material. In 1989 and 1990, defendant engaged in disputes over production of documents, culminating in an *in camera* inspection by this court.

Defendant also has expended substantial time and effort to narrow the substantive legal issues for trial. For about eight years, this case has produced a flurry of motions and countermotions. Defendant has vigorously protected its interests at great expense over this prolonged period.

At the time plaintiff moved to withdraw, defendant had pending a dispositive summary judgment motion. In November 1983, defendant filed a motion for summary judgment to dismiss the entire case. Defendant similarly filed a motion for partial summary judgment in August 1989.

Thus, defendant has both incurred great expense and subjected plaintiff to a pending summary judgment motion. Moreover, after eight years of litigation, plaintiff has moved to withdraw on the eve of trial. Exposing defendant to the uncertainty of renewed

litigation after eight years of preparation is a burden which it should not have to bear.

*Progress of Litigation*

[8] Dismissal with prejudice is appropriate where there have been extensive proceedings with a trial clearly in sight. *Ferguson,* 492 F.2d 26; *Rollison v. Washington Nat'l Ins. Co.,* 176 F.2d 364 (4th Cir.1949). The United States Court of Appeals for the Third Circuit explained that Rule 41 permits a plaintiff " to take his case out of court when no one else will be prejudiced by his doing so." *Ferguson,* 492 F.2d at 28. However, " [t]he situation is quite different when answers have been filed.... It is likewise an increasingly burdensome matter ... if a case has been prepared, trial date set and the party and his witnesses on hand and ready for trial." *Id.* at 28.

After eight years, plaintiff's motion to withdraw comes on the eve of a scheduled ten-day trial. The Claims Court has resolved over 72 motions and has conducted innumerable status conferences in court and by telephone. In less than two years, this court has narrowed the issues for trial by two summary judgment motions and two motions for reconsideration. Further, this court has scheduled a pre-trial conference, has ordered the filing of Appendix G submissions, and has scheduled a trial for October 1990. The court warned the parties that trial would occur in October without delay, and that any motions which it could not resolve by then would be addressed at trial. Plaintiff's motion could not have occurred at a later stage of these protracted proceedings.

*Plaintiff Diligence and Good Faith*

[9][10][11] If plaintiff has not prosecuted his case with diligence and good faith, it is appropriate for the court to grant a voluntary motion to withdraw with prejudice. *Pace,* 409 F.2d 331; *Walker v. Spencer,* 123 F.2d 347 (10th Cir.1941), *cert. denied,* 316 U.S. 692, 62 S.Ct. 1296, 86 L.Ed. 1763 (1942); *Thomas,* 393 F.Supp. 58. Insufficient explanation of the need for dismissal, using dismissal to deprive defendant of a ruling on a dispositive motion, and excessive delay are among the factors which justify dismissal with prejudice. *Pace,* 409 F.2d at 334. Similarly, the court should dismiss with prejudice if the motion to withdraw merely represents an attempt to relitigate under more favorable circumstances. *Thomas,* 393 F.Supp. at 70.

Plaintiff claims that it must withdraw because of a lack of financial resources. After eight years of aggressive litigation, ***136** plaintiff picked a rather inopportune time to assert its financial distress. As late as March 1990, plaintiff attempted to amend its complaint. However, plaintiff must have known since 1978, when Deuterium became an insolvent shell corporation, that the business faced financial instability. Yet, plaintiff has waited eight years, after an enormous expenditure of the court's and the Government's resources at taxpayer's expense, to announce that it has insufficient funds to fuel further litigation. This sudden shift in plaintiff's willingness to proceed, without any apparent change in Deuterium's corporate finances, casts doubt on plaintiff's reasons for withdrawal. Plaintiff's motion smacks of litigation strategy, rather than financial difficulty.

Moreover, plaintiff now seeks to withdraw its case in the face of an outstanding 1983 motion and a trial which will dispose of the remaining counts on their merits. This court has only partially resolved defendant's November 1983 summary judgment motion. At oral argument in February 1990, plaintiff reactivated this undecided portion of defendant's motion by representing that the outstanding issues in such motion should be the next subject for the court's attention. The parties have briefed the motion. This court notified the parties that it would endeavor to resolve this motion before or at trial. Now, just five months after alerting the court of outstanding dispositive issues on counts to which Deuterium never paid much attention, plaintiff seeks to withdraw its remaining counts voluntarily.

Under these circumstances, defendant should not be exposed to the uncertainty of future litigation and to the costs of beginning anew. If this court granted plaintiff's motion, plaintiff would have wiped the slate clean. After eight years of litigation and losses on several motions, this clean slate would unduly strengthen plaintiff's position at defendant's expense, if plaintiff later elected to refile. Thus, this court dismisses the remaining counts of plaintiff's amended petition with prejudice.[FN4]

FN4. In view of this court's decision on plaintiff's motion to withdraw, defendant's motion requiring plaintiff to post security for costs, filed June 12, 1990, is moot.

*In Forma Pauperis*

21 Cl.Ct. 132

**(Cite as: 21 Cl.Ct. 132)**

[12][13] Plaintiff has asked for leave to proceed *in forma pauperis* in appealing this court's dismissal of Count One. Title 28, § 1915, governs a court's authority to confer such status. Section 1915 provides in pertinent part:

Any court of the United States may authorize ... any suit ... without prepayment of fees and costs ... by a person who makes affidavit that he is unable to pay such costs....

28 U.S.C. § 1915(a) (1988).

Rule 24 of the United States Court of Appeals for the Federal Circuit's Rules of Appellate Procedure sets forth the procedures for plaintiff's request. Rule 24 requires that plaintiff file an affidavit which comports with Form 4 of the Federal Circuit's rules.

This court must deny plaintiff's request to proceed *in forma pauperis.* Section 1915 contemplates that a natural person, not a corporation like Deuterium, is entitled to proceed *in forma pauperis. See, S.O.U.P., Inc. v. FTC,* 449 F.2d 1142, 1143 (D.C.Cir.1971). The form of affidavit similarly envisions that only natural persons will make such a request in view of the questions about personal income and employment. In any event, plaintiff has not filed an affidavit which comports with the form set forth in the Federal Circuit's rules. Finally, plaintiff had sufficient resources to sue vigorously for eight years. Without any apparent change in plaintiff's finances, it now pleads financial distress on the eve of trial. Plaintiff does not provide sufficient reason to proceed *in forma pauperis.*

*Sanctions*

On August 2, 1990, the Government filed a motion asking this court to impose sanctions against plaintiff. Specifically, defendant seeks sanctions for plaintiff's motions to strike the Government's 1983 summary judgment motion, to amend the complaint ***137** in 1990, and to reconsider the court's recent opinions.

[14] Although straining at the limits of RUSCC 11, plaintiff's actions do not warrant the imposition of sanctions. The issues in this case are complex. As the parties aptly demonstrated, the law and facts of this case provided ample room for disagreement and debate. In fact, this court treated seriously plaintiff's motions for reconsideration and amendment. Plaintiff did not prevail, but a party need not succeed on the merits to escape the harshness of Rule 11 sanctions. Thus, plaintiff's actions, while at times a burden to this court and unflattering to all participants, do not rise to the level of egregiousness necessary for sanctions.

CONCLUSION

This court grants with prejudice plaintiff's motion to withdraw under RUSCC 41(a)(2). This court denies plaintiff's request to proceed *in forma pauperis* and defendant's motion for sanctions. The court directs the Clerk to dismiss plaintiff's amended petition.

No costs.

Cl.Ct.,1990.
Deuterium Corp. v. U.S.
21 Cl.Ct. 132

END OF DOCUMENT

# Exhibit C

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November 1, 2006

VIA ELECTRONIC FILING

PUBLIC VERSION

The Honorable Marilyn R. Abbott
Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112-F
Washington, D.C. 20436

Re: Inv. No. 337-TA-572, *Certain Insulin Delivery Devices, Including Cartridges Having Adaptor Tops, and Components Thereof*

Dear Secretary Abbott:

Enclosed for filing on behalf of Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc. (collectively, "Complainants"), please find the public version of Complainants' Response to Respondents' Motion to Sanction and Reply in Support of Complainants' Motion to Withdraw with attached Declaration of Brendan G. Woodard containing Exhibits 1-7.

Respectfully submitted,

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*Attorneys for complainants Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc.*

**UNITED STATES INTERNATIONAL TRADE COMMISSION**
**WASHINGTON, D.C.**

**Before the Honorable Sidney Harris**
**Administrative Law Judge**

| | |
|---|---|
| In the Matter of<br><br>CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTOR TOPS, AND COMPONENTS THEREOF | Investigation No. 337-TA-572 |

**COMPLAINANTS' RESPONSE TO RESPONDENTS' MOTION TO SANCTION AND REPLY IN SUPPORT OF COMPLAINANTS' MOTION TO WITHDRAW**

Complainants Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc. (collectively, "Complainants" or "Novo Nordisk") hereby respond to respondents sanofi-aventis Deutschland GmbH, sanofi-aventis, and Aventis Pharmaceuticals, Inc. (collectively "Respondents" or "Aventis") Motion to Sanction Complainants and Memorandum in Support Thereof filed on October 13, 2006 ("Respondents' Motion"). Complainants also hereby reply to Aventis's response to Complainants' Motion to Withdraw Complaint and Terminate the Investigation ("Complainants' Motion to Withdraw"),[1] which Respondents do not oppose. (Resp. Br. at 2.)[2]

## I. SUMMARY

At the outset, Respondents tellingly fail to cite any Commission law, rule, regulation,

[1] On October 17, 2006, Complainants filed a Motion for Leave to File a Reply Brief in Support of their Motion to Withdraw Complaint and Terminate the Investigation.

[2] Respondents' Motion to Sanction, and Memorandum in Support thereof, are cited herein as "(Resp. Mot. at ___.)", and "(Resp. Br. at ___.)", respectively.

decision, or other legal authority to support their baseless motion to sanction. Although Respondents indicated that they filed "[p]ursuant to Rule 210.4," Respondents wholly failed to comply with that very rule, and blatantly ignored additional Commission practice, procedure, and precedent. Respondents' Motion should thus be stricken or denied for these reasons alone.

Complainants' Response herein, by contrast, is fully supported by both legal citations and documents. Unable to support their Motion with any legal authority, Respondents resort to making wild accusations regarding discovery and the merits of the Complaint, all unsupported, in order to avoid the reason for Complainants' Motion to Withdraw: the failure of Respondents' accused device in the United States market. Respondents have made frivolous demands on the Commission and raised disingenuous issues necessitating the wastage of both the Commission's precious resources, as well as Complainants' resources for having to file this Response. In addition to being precluded procedurally, Respondents' Motion is without substantive merit and was clearly submitted solely to harass Complainants. Respondents' Motion should therefore be summarily denied.

## II. RESPONDENTS DESERVE TO BE SANCTIONED FOR IGNORING COMMISSION PRACTICE, PROCEDURE, AND PRECEDENT

### A. Respondents Failed to Follow Well-Established Commission Process

Denial of Respondents' Motion is justified on several procedural grounds, from ignoring Commission Rules to failing to acknowledge Commission precedent.

#### 1. Failure to Comply with Commission Requirements Before Filing for Sanctions

As noted above, Respondents indicate that they were filing "[p]ursuant" to Commission Rule 210.4. (Resp. Mot. at 1.) Consistent with a pattern demonstrative of their reckless disregard for Commission process and precedent, described in detail infra, Respondents filed

"[p]ursuant" to a rule with which they failed to comply.[3] Commission Rule 210.4 requires that prior to filing any motion for sanctions with the Commission or one of its Administrative Law Judges, the moving party must provide the allegedly offending party seven days within which to "withdraw . . . or appropriately correct" its "challenged paper, claim, defense, contention, allegation, or denial." 19 C.F.R. § 210.4. Contrary to this requirement, Respondents provided no such opportunity to Complainants.

Further, in order to comply with Commission Rule 210.4, Respondents presumably would have requested that Complainants withdraw their Complaint. Because Complainants had already moved to withdraw their Complaint (which Respondents do not oppose) prior to the filing of Respondents' motion to sanction, Respondents could not possibly have met this condition precedent in order to proceed under Commission Rule 210.4. Commission Rule 210.4 was not available to Respondents once Complainants moved to withdraw.

2. Failure to Comply with Commission Process for Handling Discovery Disputes

Equally demonstrative of Respondents' lack of regard for Commission rules of practice and procedure, Respondents seek to sanction Complainants for withdrawing a complaint rather "meet[ing] and confer[ring]" regarding a discovery grievance. (Resp. Mot. at 1.) Respondents base their motion for sanctions on Rule 210.4(d). Rule 210.4(e), however, states that "[p]aragraphs (c) and (d) of this section [210.4] do not apply to discovery requests, responses, objections, and motions that are subject to provisions of Secs. 210.27 through 210.34." 19

[3] Moreover, Aventis moved to sanction pursuant to "the inherent powers of the International Trade Commission (ITC) . . . ." (Resp. Mot at 1.) Aventis, however, failed to cite any authority for the assertion that the ITC has the inherent powers to sanction Complainants. See Certain Point of Sale Terminals and Components Thereof, Inv. No. 337-TA-524, Commission Opinion at 13 (August 23, 2006) (In rebuffing an argument that the Commission has inherent authority to impose sanctions, the Commission stated: "Nor does the case law cited by respondents support the proposition that the Commission has inherent authority outside of Commission rule 210.4 to impose sanctions, since the case law they cite relates to courts, not administrative agencies.")

C.F.R. § 210.4(e).

Again, Respondents cite Commission rules that do not support the proposition for which they assert them but, instead, undercut their Motion.

B. Respondents Failed to Acknowledge and Follow Well-Established Precedent

1. Failure to Acknowledge Commission Precedent Regarding Termination with "Prejudice"

Respondents' request that the investigation be terminated with "prejudice" is contrary to existing Commission authority. By seeking termination "with "prejudice" in response to Complainants' Motion to Withdraw, Respondents seek from the Commission a sanction which the Commission has clearly established is beyond its statutory authority. Semiconductor Light Emitting Devices, Components Thereof and Products Containing Same, Inv. No. 337-TA-444 Order # 7 at 3 (January 27, 2001) (citing Certain Bar Clamps, Bar Clamp Pads, And Related Packaging, Display, And Other Materials, Inv. No. 337-TA-429, Commission Opinion at 5-7 (Public Version Feb. 13, 2001) ("section 337 does not permit us to terminate an investigation 'with prejudice' based upon withdrawal of a complaint.")). Respondents utterly ignore this clear precedent and nevertheless request termination with "prejudice." (Resp. Br. at 2.)

2. Failure to Comply with Commission Precedent Regarding "Safe Harbor"

Equally as troubling and demonstrative of Respondents' lack of regard for the well-established precedent of this Commission is the fact that Respondents felt compelled to file their motion to sanction in the face of Complainants' motion to withdraw. Respondents' Motion is clearly barred by the "safe-harbor" provision of Rule 210.4(d)(1) as articulated in a long and consistent series of Commission decisions. See, e.g., Power Supply Controllers and Products Containing Same, Inv. No. 337-TA-541; Order No. 23 (January 18, 2006); Certain Weather Stations and Components Thereof, Inv. No. 337-TA-537, Order No. 8 (Oct. 12, 2005) ("if the

sanctionable conduct concerns the filing of a complaint in a section 337 action and the complainant has moved to withdraw the complaint before the sanctions motion has been filed, then the motion for sanctions is preempted by the safe harbor rule.").

Additionally, Complainants note that the Commission Trial Staff, in support of its opposition to Respondents' request for termination with prejudice, properly cited Certain Network Communications Systems for Optical Networks and Components Thereof, Inv. No. 337-TA-535, Order No. 6 (June 7, 2005) (unreviewed initial determination) (granting motion to terminate investigation based on withdrawal of the complaint); Certain Shirts with Pucker-Free Seams, Inv. No. 337-TA-517, Order No. 5 (Nov. 29, 2004) (unreviewed initial determination) (granting motion to terminate investigation as to three of the four patents at issue). Moreover, "[w]here a complainant moves to withdraw the complaint or certain allegations thereof, public policy supports termination in order to conserve public and private resources." Certain Semiconductor Timing Signal Generator Devices, Components Thereof, and Products Containing Same, Inv. No. 337-TA-465, Order No. 8 at 2 (April 16, 2002) (unreviewed initial determination.)

3. Failure to Comply with the Commission's "Objectively Reasonable" Standard

Respondents also failed to comply with the Commission's recent interpretation of 19 C.F.R. § 210.4. Less than two months ago, the Commission specifically ruled that the appropriate test for sanctions is "whether the representation or disputed portion thereof was objectively reasonable under the circumstances." Certain Point of Sale Terminals and Components Thereof, Inv. No. 337-TA-524 Commission Opinion at 10 (August 23, 2006). Nowhere have Respondents even acknowledged this standard, nor have they attempted to apply it.

Respondents' Motion is clearly defective on procedural grounds, and accordingly, should be stricken or summarily dismissed for these reasons alone.

## III. RESPONDENTS' UNSUPPORTED MOTION IS FRIVOLOUS AND DEVOID OF SUBSTANTIVE MERIT

Respondents' Motion is also defective on substantive grounds. No party should be allowed to file with impunity motions such as this that have no "good faith" basis in law or fact.

### A. Respondents Cannot Deny that Complainants' Motion to Withdraw Was Justified For Market-Based Reasons

Just as Respondents' motion for sanctions was cavalier regarding Commission process and precedent, it is equally cavalier with the facts. For example, Respondents erroneously assert that Complainants filed their Complaint in order to disrupt the launch of OptiClik®.[4] (Resp. Br. at 2.) This assertion is easily dismissed in light of the timing of the launch of OptiClik® in the United States, which was more than one year before the Complaint was filed.[5]

Respondents would also have this Court believe that Complainants withdrew their Complaint due to Respondents' assertions regarding invalidity or inequitable conduct. The allegations in Respondents' Motion, however, are nothing more than unsupported legal arguments. Rather than a fear of rulings of invalidity or unenforceability, Complainants' motion to withdraw was based in whole on two premises.

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[4] [

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[5] Notably, Respondents filed a lawsuit against Complainants in the District of New Jersey just prior to the March 2006 launch of their long-acting insulin product, Levemir® . Respondents alleged Lanham Act and false advertising causes of action, and sought preliminary relief, which the Court rejected. Ironically, Respondents voluntarily dismissed their complaint in that action on October 11, 2006, two days before filing the instant motion for sanctions here.

First and foremost, changing market conditions in the insulin delivery device market warranted the termination of this investigation. Given that the infringing OptiClik device is in the midst of losing market share for market-based reasons, Complainants were faced with a market driven fait accompli. The market is already in the process of providing the relief sought by Complainants' in this investigation: to enjoin Respondents from distributing and/or selling a device in the United States that infringes Complainants' intellectual property. Rather than waste the Commission's and parties' precious resources as Respondents have done with their current Motion, Complainants prudently moved to withdraw their Complaint.[6]

Complainants could not have foreseen the current market conditions when the Complaint was filed in May 2006. Only recently did Complainants become aware of changes in market conditions that include: (i) the severity of the production problems related to the infringing OptiClik® device – which is manufactured for Respondents by Ypsomed AG ("Ypsomed"), (ii) the weak demand for the infringing OptiClik® device in the United States, and (iii) Aventis's development and expected launch of its own insulin injection pen. Now that the "business picture has changed"[7] for OptiClik®, and given the injunctive remedy available from an ITC investigation, Complainants decided that expending additional resources was no longer warranted.

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[6] Moreover, Complainants continue to seek monetary damages and an injunction against Respondents in the District of Delaware in an infringement lawsuit on an unrelated United States patent, U.S. Patent No. 6,582,408 (the "Delaware litigation"). The Delaware litigation is different than this proceeding because, among other things, monetary damages are at issue there.

[7] See Ypsomed AG Conference Call, Sept. 14, 2006, http://www.ypsomed.com/en/medien_investoren/investoren/494.html ("On one hand you [i.e., Ypsomed] were building up your capacity to be able to handle a higher level of activity and I presume with active communication with Sanofi Aventis and now the business picture has changed . . . .").

A brief near term history regarding the OptiClik® device is instructive. On July 4, 2006, Ypsomed announced that it had "suspended" the production of OptiClik® for eight (8) weeks. (Woodard Decl. Ex. 1.)[8] Then, in an Announcement on September 14, 2006, Ypsomed formally acknowledged "production problems" with the OptiClik® device. (Woodard Decl. Ex. 2.) Also, on September 14, 2006, Ypsomed revealed the weak demand for Aventis's infringing OptiClik® devices in the United States, noting:

> • "Sanofi-Aventis has reduced orders and order forecasts for 2006/07 for insulin pens."
>
> • "The main reason given by Sanofi-Aventis for their reduced order forecast is a slower . . . uptake and overall weaker demand for the semi-disposable OptiClik ® pen in the U.S. market . . ."
>
> • "The main reason stated by Sanofi-Aventis for this shortfall is a weaker demand, especially for the OptiClik® pen in the US market . . . ."

(Woodard Decl. Exs. 2, 3.) Finally, as noted in an Ypsomed conference call with media and investors on September 14, 2006, "Sanofi Aventis is pushing ahead with the development of its own injection pen."[9]

Given OptiClik®'s unflattering outlook in the United States market, and Respondents' development and expected launch of a new injection pen to replace the OptiClik® device, Complainants moved to withdraw their Complaint on October 5, 2006.

Secondly, as any prudent litigator should understand, Complainants were loath to continue in a process whereby they would be required to provide Respondents gratis the benefit of their infringement analysis when the relief to be obtained was already being delivered by the marketplace in which the infringing OptiClik® device competes. Complainants have no

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[8] Citations to "Woodard Decl." are to the accompanying Declaration of Brendan G. Woodard and exhibits thereto, which are being filed herewith.

[9] See Ypsomed AG Conference Call, Sept. 14, 2006, http://www.ypsomed.com/en/medien_investoren/investoren/494.html

intention of being baited into a protracted and unnecessary debate on the validity and enforceability of the patent-in-suit, which at this stage amounts to nothing more than Respondents' unsupported attorney rhetoric. Nevertheless, as demonstrated below, Respondents' assertions on the merits are easily exposed as paper-thin.

B. Respondents' "Million Dollar" Exaggeration

No less disturbing is Respondents' unsupported $1 million figure. (Resp. Br. at 3-4.) Respondents assert that Complainants committed "discovery abuses" by refusing to produce documents, thereby somehow "causing" Respondents to serve an astounding 356 document requests and "forcing" Respondents to "spend over $1 million dollars" to obtain documents. (Id.) Aventis's only support for these wild allegations is a numbers comparison: Aventis produced 600,000 pages of documents, while Novo Nodisk's production comprised some 37,000 pages. (Id.) Respondents' allegations, however, are misleading and hypocritical. A review of the facts demonstrates the truth: Respondents, not Complainants, failed to meet their discovery obligations.

Initial written discovery was exchanged in July 2006. Complainants served 100 ITC-specific document requests, while Respondents served an overwhelming 303 document requests.[10] (Resp. Ex. B.) The parties met and conferred shortly thereafter, agreeing to a number of discovery-related issues including, inter alia, to exchange documents on August 25, 2006. (Woodard Decl. Ex. 4.)

On August 25, 2006, the agreed-upon production date, Complainants produced nearly 40,000 pages of relevant, technical and financial documents responsive to Respondents' requests. Complainants' documents related specifically to this proceeding and were not duplicative of

[10] Respondents served 53 additional requests on September 19, 2006.

documents produced earlier in the Delaware litigation. Despite the excessively broad and unduly burdensome nature of Respondents' requests, many of which sought wholly irrelevant information, Complainants made a concerted, good-faith, case-specific effort to collect and timely produce responsive materials. This effort and subsequent efforts to supplement included, among other things, trips to Novo Nordisk facilities in Denmark and North Carolina to identify and collect relevant, responsive documents. (Woodard Decl. ¶ 6.) Because many of the documents collected were in Danish, Complainants' production effort also included the services of several Danish translators. (Woodard Decl. ¶ 7.)

By contrast, Respondents failed to produce a single document on the August 25, 2006 deadline. Complainants received no documents from Respondents until September 11, 2006, and Respondents produced these documents only after being prompted by Complainants. (Woodard Decl. Ex. 5.) In fact, Respondents withheld the vast majority of their production until September 15, 2006, three weeks after the agreed-upon due date. (Id.)

Further, Respondents' production on September 15, 2006 was nothing more than a "data dump" of 600,000-plus pages of documents, nearly 100% of which were already in Complainants' possession.[11] Indeed, Respondents merely re-produced documents they had previously produced in the unrelated Delaware litigation. (Woodard Decl. Ex. 5, 6.) Respondents even stated that, at least as late as September 8, 2006, they had not even searched for (much less produced) documents responsive to Complainants' ITC-specific requests as required by Commission Rules. (Id.) Respondents sardonically noted that they would be simply reproducing their Delaware production, which is exactly what they did. (Id.)

[11] Based on Complainants' review of Respondents' ITC production, Respondents' Delaware and ITC productions differ by a mere 50 or so documents. (Woodard Decl. Ex. 8.)

Respondents will likely try again to shroud the truth by arguing that the OptiClik® device was at issue in both the Delaware and ITC proceedings. While OptiClik® is at issue in the Delaware proceeding, the two proceedings involve completely different patents, inventions, and available remedies, and accordingly, the concomitant legal issues are also different. Complainants' document requests recognized this, and so should have Respondents. Indeed, Complainants' ITC discovery requests were separate and tailored to these and other issues pertinent only to ITC proceedings. Conversely, given such differences between the ITC and Delaware cases, Respondents' Delaware production necessarily contains documents that are neither responsive to Complainants' ITC requests nor relevant to the issues in the ITC case.[12] Respondents' mere re-production of their Delaware documents is especially surprising and disingenuous given that they have always maintained that the Delaware and ITC proceedings are separate and distinct.

Complainants should not have had to assume the costly and time-consuming burden of wading through Respondents' "data dump" of Delaware documents to determine which documents are responsive to Complainants' ITC requests. That burden was Respondents'. Under Commission Rules, Respondents were obligated to search for and produce relevant, responsive material in the ITC proceeding. Respondents having failed to meet these obligations, Complainants requested, on several occasions, that Respondents (1) confirm whether they had searched for documents responsive to Complainants' ITC requests apart from their Delaware searches and production (aside from the 50 or so aforementioned documents), (2) identify by Bates number the specific documents in their Delaware production that were responsive to

[12] For example, Respondents' Delaware production (and therefore also its ITC "data dump" production) contains hundreds and hundreds of patents and patent applications, comprising thousands and thousands of pages of material that cannot possibly be relevant to the issues in the ITC proceeding, nor are they responsive to Complainants' ITC document requests.

Complainants' ITC requests, and (3) because Respondents inexplicably used different Bates numbering for their two productions even though the documents are the same, provide a means to cross-reference the corresponding documents. (Woodard Decl. Ex. 6.) Respondents ignored all of these requests.

In the meantime, despite their own lack of production, Respondents continued to serve numerous, excessively broad and unduly burdensome requests to which Complainants worked to respond. Complainants had no, nor have any, reason to "defend [their] conduct," as Respondents assert. (Resp. Br. at 4.) Respondents never presented their alleged "Conference Agenda" (Resp. Ex. D) to Complainants, nor did they ever raise the vast majority of the specific document issues set forth therein. The parties had never even met and conferred concerning any of the stated issues, as required by the Ground Rules, although Complainants remained open and willing throughout the entirety of the proceeding to discuss any perceived discovery issues that Respondents may have had. (Woodard Decl. Exs. 5, 6.) To the contrary, Complainants had willingly agreed to provide some of the requested information set forth in the Agenda, and were in the process of doing so. (Woodard Decl. Ex. 5 at 3.) The timing of Complainants' Motion to Withdraw is in no way related to Respondents' requested meet and confer.

Complainants made a good faith effort throughout the course of discovery to search for and produce relevant documents and information responsive to Respondents' vastly overbroad requests. This included a second, timely document production on October 3, 2006, responsive to Respondents' second set of requests. Given Respondents' numerous requests, Complainants' production was ongoing at the time they filed their Motion to Withdraw and Terminate. Respondents, by contrast, (i) failed to timely produce documents on the agreed upon deadline, (ii) failed to produce, or even search for, documents pertinent to the issues and Complainants'

specific requests in this investigation, and instead (iii) merely reproduced their production from the Delaware case without any means to identify ITC-specific material, as Complainants requested. In the end, it is Respondents' conduct during discovery, not Complainants', that should be evaluated for sanctions.[13]

C. Respondents' Attorney Arguments Concerning Infringement, Validity and Enforceability Should Be Disregarded

Respondents' arguments regarding infringement, validity, and enforceability are legally and factually unsupported, and in any event, are insufficient and miss the mark. Respondents' unsupported legal arguments are a transparent effort to portray Complainants' conduct as somehow sanctionable, and as such are inappropriate. Although addressing these arguments in detail far exceeds the proper scope of Respondents' Motion, the impropriety of these arguments calls for a brief response.

Respondents' non-infringement allegation, for example, rests upon a fundamental and reversible error of law: a comparison of the infringing OptiClik® pen system with the figures of the '027 patent and with Novo Nordisk's commercial embodiment of the '027 patent. (Resp. Br. at 5-6). As Respondents are surely aware, comparing the infringing OptiClik® system with anything but the claims of the '027 patent is irrelevant.[14] Yet Respondents style their motion as though the pending investigation involved a case of trade dress infringement. This is a case of

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[13] In Certain Agricultural Tractors, after Respondents refused to withdraw its Motion for sanctions or motion to dismiss, the ALJ granted Complainants motion for sanctions and "[found] that respondent's Motion to Dismiss and Motion for Sanctions contained legal contentions that are not warranted by existing law and include allegations that have no evidentiary support." Certain Agricultural Tractors Under 50 Power Take-Off Horsepower, Inv. No. 337-TA-380, Order No. 69 (Jan. 21, 1999).

[14] Respondents imply, for example, that the adaptor top of the '027 patent must resemble the one in the figures of the patent. The '027 patent, however, makes clear that the "plastic [adaptor] top may surround only the neck part of the cartridge or it may cover a bigger or smaller part of the cartridge and even form a part of the housing of a syringe . . ." (Woodard Decl. Ex. 7 at column 2, lines 22-25.)

infringement of a utility patent and requires application of the actual language of the claims of the patent-in-suit. Respondents' attempt to move the ITC on the basis of arguments like this one – which is not only meritless, but misleading – is irresponsible and should be rejected.

That Respondents gloss over the actual language of the claims of the '027 patent is no innocent error as to the law of patent infringement, but is essential to their frivolous charge of inequitable conduct. That charge rests upon an assortment of easily dismissed accusations. Respondents fail to offer so much as a shred of support for their assertion that anyone involved in the preparation or prosecution of the '027 patent intentionally misled the U.S. Patent and Trademark Office.

Respondents' frivolous inequitable conduct charge is based on supposed knowledge (by "Novo") of (1) dental syringes, (2) the Insuject pen system, and (3) a device called NovoPen® II. An additional charge is based, apparently, upon hearsay attributed to one Bernard Sams. None of these allegations is supported by any showing.

Respondents' motion contends that the Insuject® device included "adaptor tops exactly like the claims of the '027 patent." (Resp. Br. at 7-8.) Yet Respondents never actually refer, as it must, to either (1) the actual language of the '027 patent claims or (2) the relevant portions of the structure of the Insuject® device. Respondents' characterization of Insuject® itself is also factually incorrect. Far from disclosing the invention of the '027 patent claims, which called for a specific structure including an adaptor top, the Insuject® cartridge contained no adaptor whatsoever. To the contrary, Insuject® provided a non-standard glass cartridge having a plastic closure for keeping a pierceable membrane on the cartridge. The non-standard Insuject® cartridge, when sealed with the plastic cap, could be used only with the Insuject® device.

In other words, Insuject® had no adaptor to conform its non-standard cartridge configuration for use with any device other than Insuject®. The cartridges were manufactured for the Insuject® pen alone. But the '027 patent, including its claims, relate to the adaptation of an exchangeable and standard cartridge to a particular delivery device.

Moreover, Respondents' Motion neglects to inform the Court that the structure of the Insuject® was, in fact, presented to the U.S. Patent and Trademark Office. It is prominently and concisely described at the beginning of the '027 patent in the section entitled "Description of the Related Art." That language begins by describing a standard cartridge:

> In a standard cartridge the outer end of the bottleneck is provided with an external flange supporting the rubber membrane, and this membrane is sealingly secured over the opening of the neck against the flange by a metal cap . . .

(Woodard Decl. Ex. 7 at column 1, lines 20-23.)

The Description of the Related Art section of the '027 patent then comments on the prior art in the following way:

> As new types of pen syringes were developed the cartridges or at least the neck thereof was given different shapes to accommodate these types of syringes. The use of plastic closures instead of the standard metal cap has made it necessary to design the flanges for cooperation with such plastic tops which demand a greater accuracy of the glass flange if a reliable sealing shall be obtained. Consequently, the different insulin types each have to be marketed in different types of cartridges whereby the manufacturing and the stockpiling is made complicated."

(Id. at column 1, lines 28-38 (emphasis added).)

Cartridges for use with the Insuject® pen used "plastic closures" of precisely the type described in the passage quoted in the '027 patent. The claims of the '027 patent thus set forth a distinct and patentable improvement over the type of device described in the opening lines of the patent: the claimed invention used a standard exchangeable cartridge having a standard metal cap, and then also provided for an adaptor top to permit that standard cartridge to be tied to a

particular type of pen – precisely the opposite of the Insuject approach. A separate deficiency in Respondents' argument is that they has not shown, as is required to meet their heavy burden, that the Insuject® pen was even available as prior art to the '027 patent.

Respondents also imply that NovoPen® II would have been material to the examination of the '027 patent claims. NovoPen® II, however, did not include any kind of adaptor. NovoPen® II included only a holder for receiving a cartridge that could have been used in other devices. In other words, nothing in the NovoPen® II device adapted an exchangeable cartridge to a particular delivery device, as described and claimed in the '027 patent. Again, Respondents' support for this allegation is mere attorney argument that is factually, as well as legally, misleading.

As for Respondents' meager comments on the '027 claims themselves, they amount to nothing more than attorney hand-waving. No actual claim language, much less an element-by-element analysis, is even alluded to in Respondents' Motion.

The allegations underpinning Respondents' Motion, unsupported by fact or law, are easily dismissed. They provide absolutely no basis for justifying the extraordinary and unprecedented measures requested by Respondents. Respondents' Motion, therefore, should be denied.

## IV. CONCLUSION

Respondents' Motion to Sanction should be summarily dismissed. In truth, it is Respondents who deserve sanctioning for filing a motion that blatantly ignores Commission procedure, practice, and precedent, and in addition has no "good faith" basis in law or fact. Respondents' conduct in filing their Motion is remarkably similar to their pattern of abusive discovery conduct. Unlike Respondents, however, Complainants recognize that they cannot ask

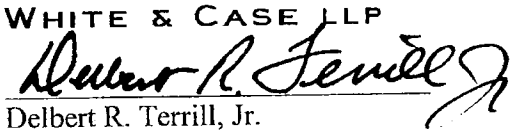
this Court and the Commission to contravene its Rules of Practice and Procedure and sanction Respondents for such discovery abuses.

Accordingly, for the foregoing reasons, Complainants respectfully submit that (1) Complainants' Motion to Withdraw Complaint and Terminate the Investigation, which Respondents do not oppose, should be granted, (2) Respondents' request that the investigation be terminated "with prejudice" should be denied, and (3) Respondents' Motion to Sanction should be denied.

Dated: October 24, 2006
Washington, DC

Respectfully submitted,

WHITE & CASE LLP



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*Attorneys for complainants Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on November 1, 2006, a copy of **COMPLAINANTS' RESPONSE TO RESPONDENTS' MOTION TO SANCTION AND REPLY IN SUPPORT OF COMPLAINANTS' MOTION TO WITHDRAW WITH ATTACHED DECLARATION OF BRENDAN G. WOODARD CONTAINING EXHIBITS 1-7 (PUBLIC VERSION)** was served on the following parties as indicated:

The Honorable Marilyn R. Abbott
Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W., Room 112-F
Washington, DC 20436

**By Electronic Filing**

The Honorable Sidney Harris
Administrative Law Judge
U.S. International Trade Commission
500 E Street, S.W., Room 317-H
Washington, DC 20436

**Two (2) Copies by Hand Delivery**

Rett Snotherly, Esq.
Office of Unfair Import Investigations
U.S. International Trade Commission
500 E Street, S.W., Room 401-Q
Washington, D.C. 20436

**One (1) Copy by Hand Delivery and Electronic Mail**

**Counsel for Respondents Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis, and Aventis Pharmaceuticals, Inc.**

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Arthur Wineburg
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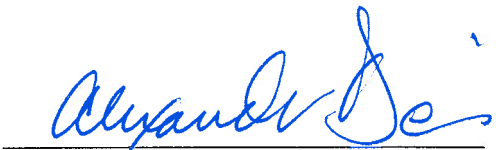


Alexander Dennis

**UNITED STATES INTERNATIONAL TRADE COMMISSION**
**WASHINGTON, D.C.**

**Before the Honorable Sidney Harris**
**Administrative Law Judge**

| | |
|---|---|
| In the Matter of:<br><br>CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTOR TOPS, AND COMPONENTS THEREOF | Investigation No. 337-TA-572 |

**DECLARATION OF BRENDAN G. WOODARD**

I, Brendan G. Woodard, declare as follows:

1. I am an associate with the law firm of White & Case LLP, counsel for Complainants Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc. (collectively, "Complainants"), in this investigation. I offer this declaration in support of Complainants' Response to Respondents' Motion to Sanction and Reply in Support of Complainants' Motion to Withdraw.

2. Attached hereto as Exhibit 1 is a true and correct copy of an Ypsomed Holding AG Press Release, dated July 4, 2006.

3. Attached hereto as Exhibit 2 is a true and correct copy of an Ypsomed Holding AG Information on Ad-hoc Announcement, dated September 14, 2006.

4. Attached hereto as Exhibit 3 is a true and correct copy of an Ypsomed Holding AG Press Release, dated September 14, 2006.

5. Attached hereto as Exhibit 4 is a true and correct copy of correspondence from counsel of Complainants and Respondents to Judge Sidney Harris, dated July 26, 2006.

6. The document production effort conducted on Complainants' behalf included, among other things, trips to Novo Nordisk facilities in Denmark and North Carolina to identify and collect relevant, responsive documents.

7. The document production effort conducted on Complainants' behalf included the services of several Danish translators.

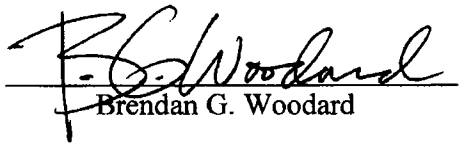
8. Attached hereto as Exhibit 5 is a true and correct copy of correspondence from Brendan G. Woodard to Alison J. Baldwin and Nicole Keenan, dated September 20, 2006.

9. Attached hereto as Exhibit 6 is a true and correct copy of correspondence from Brendan G. Woodard to Alison J. Baldwin, dated September 22, 2006.

10. Attached hereto as Exhibit 7 is a true and correct copy of United States Patent No. 5,693,027.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in New York, NY, on October 24, 2006.



Brendan G. Woodard

# Exhibit 1

YPSOMED
SELFCARE SOLUTIONS

Ypsomed Holding AG
Brunnmattstrasse 6
PO Box
3401 Burgdorf / Switzerland
Tel. +41 34 424 41 11
Fax +41 34 424 41 55
www.ypsomed.com

# PRESS RELEASE

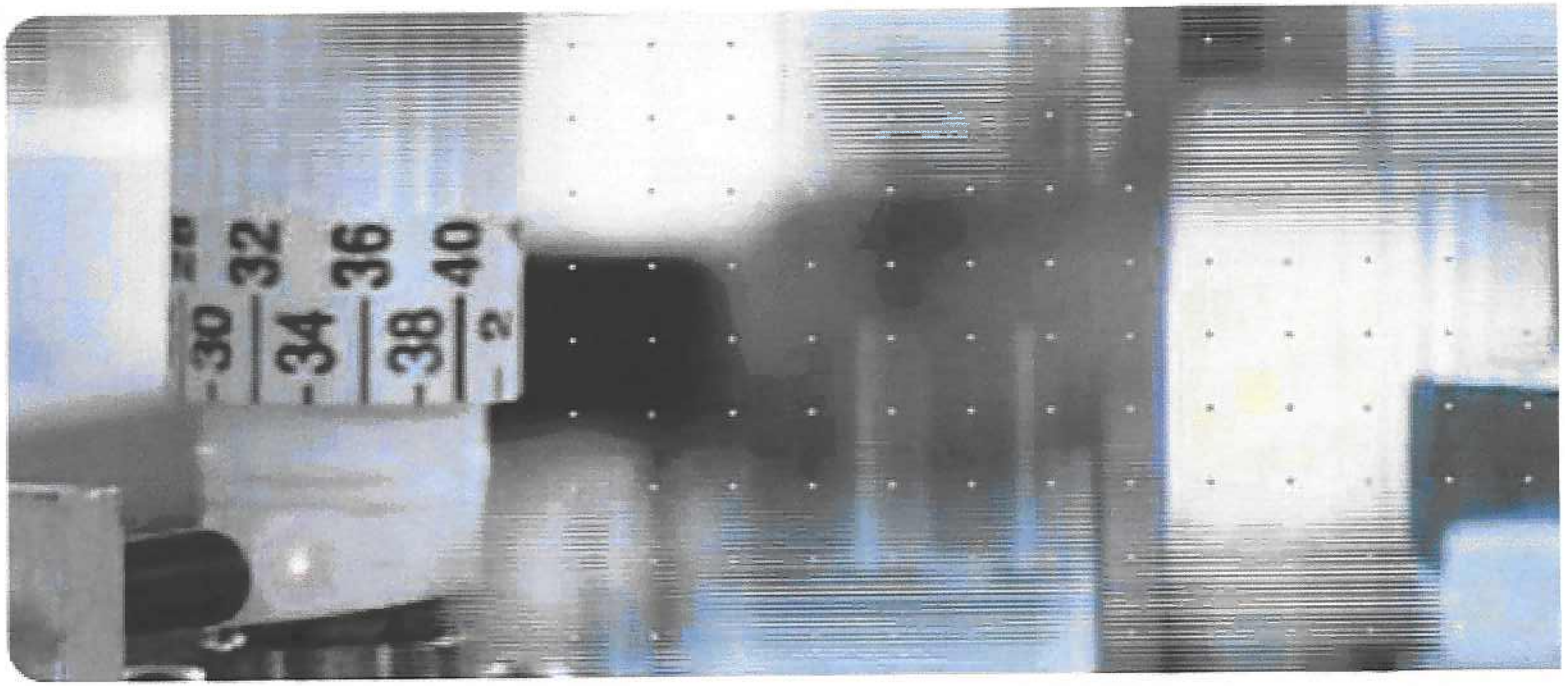
## Ypsomed's OptiClik® pen production back on track

Burgdorf, 4th July 2006, 7:30 a.m. – Ypsomed has resumed production of the dialling unit for the OptiClik® pen system as planned following an intensive optimisation phase. Matthew Robin, CEO of Ypsomed, explains: "The adjustments in the production have been successfully implemented, enabling Ypsomed to resume deliveries of newly produced OptiClik® pen systems to sanofi-aventis. We have also increased OptiSet® production at both the Burgdorf and Solothurn sites to 24 hours seven days a week." Production of the OptiClik® dialling unit had to be suspended for a total of eight weeks in order to carry out the technical adjustments to the manufacturing process.

Further information is available from Daniel Kusio, Head of Investor & Public Relations at Ypsomed Holding AG. Tel. +41 34 424 41 43 or Tel +41 34 424 41 11. This press release and further documents are available in electronic form at www.ypsomed.com.

# Exhibit 2

# Information on Ad-hoc Announcement




Solothurn, 14th September 2006

YPSOMED
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# Important Notice

YPSOMED
SELFCARE SOLUTIONS

The information contained in this document has not been independently verified and no representation or warranty, express or implied, is made to, and no reliance should be placed on, the fairness, accuracy, completeness or correctness of the information or opinions contained herein. None of Ypsomed Holding AG, its advisors or representatives, or their respective affiliates shall have any liability whatsoever for any loss whatsoever arising from any use of this document, or its content, or otherwise arising in connection with this document. This document does not constitute, or form part of, an offer to sell or a solicitation of an offer to purchase any shares and neither it nor any part of it shall form the basis of, or be relied upon in connection with, any contract or commitment whatsoever.

This document contains forward-looking statements which involve risks and uncertainties. These statements may be identified by such words as “may”, “plans”, “expects”, “believes” and similar expressions, or by their context. These statements are made on the basis of current knowledge and assumptions. Various factors could cause actual future results, performance or events to differ materially from those described in these statements. No obligation is assumed to update any forward-looking statements.

# Agenda

YPSOMED
SELFCARE SOLUTIONS

- **Ad-hoc Announcement – Sales and profit below expectations**
- Richard Fritschi appointed as new CEO
- Questions and Answers
- Additional Information on company and products

# Ad-hoc Announcement

YPSOMED
SELFCARE SOLUTIONS

- The production problems and interruption related to the OptiClik® reusable module have a negative effect on sales and EBIT in the first half year 2006/07.
- Sanofi-Aventis has reduced orders and order forecasts for 2006/07 for insulin pens.
- The main reason given by Sanofi-Aventis for their reduced order forecast is a slower uptake and overall weaker demand for the semi-disposable OptiClik ® pen in the US market as well as a delayed launch of the OptiClik® pen in certain European countries.
- Ypsomed will inform on 9th November 2006 on the first half year results and further details in respect to the business year 2006/07.

# Agenda

YPSOMED
SELFCARE SOLUTIONS

- Ad-hoc Announcement – Sales and profit below expectations
- **Richard Fritschi appointed as new CEO**
- Questions and Answers
- Additional Information on company and products

# Richard Fritschi appointed new CEO

YPSOMED
SELFCARE SOLUTIONS

- 15 years of professional experience in medtech (Zimmer, Centerpulse and SulzerMedica)
- Proven international leadership and M&A track record, i.e. Zimmer take-over of Centerpulse, several large acquisitions and turnaround situation with Sulzer Medica
- International sales responsibility (e.g. at Zimmer with CHF 1.3 billion in sales and 2'000 employees)
- Vice-president of the board of directors at Vetropack Holding AG
- 46 years old, married, Swiss nationality

# Richard Fritschi – Professional Career

YPSOMED SELFCARE SOLUTIONS

- 2003-2006 Zimmer, President Europa & Australasia (CHF 1.3 billion in sales and 2'000 employees)
- 2001-2003 SulzerMedica/Centerpulse, President Europe, Asia & Latin America
- 1998-2000 Sulzer Orthopedics, General Manager Global Sales (CHF 800 million in sales)
- 1991-1998 Allo Pro AG, Vice President Finance & Controlling, international Team

# Agenda

YPSOMED
SELFCARE SOLUTIONS

- Ad-hoc Announcement – Sales and profit below expectations
- Richard Fritschi appointed as new CEO
- **Questions and Answers**
- Additional Information on company and products

# Questions & Answers

YPSOMED
SELFCARE SOLUTIONS

# Agenda

YPSOMED
SELFCARE SOLUTIONS

- Ad-hoc Announcement – Sales and profit below expectations
- Richard Fritschi appointed as new CEO
- Questions and Answers
- **Additional Information on company and products**

# Ypsomed's Growth Strategy

YPSOMED SELFCARE SOLUTIONS

- Ypsomed is the technology leader and number one independent manufacturer of injection systems worldwide.
- Ypsomed's strategy is focused to maintain and expand its position in the future.
- In order to achieve this objective, Ypsomed will…
  - Improve production capacity in order to meet existing and future demand for the OptiClik®, OptiSet® and OptiPen® Pro insulin pens
  - Expand production capacities for pen needles and increase sales
  - Broaden the revenue base of injection systems by launching new pen systems
  - Strengthen Ypsomed's diabetes business
  - Diversify revenue streams by evaluating and executing potential acquisition targets within the scope of Ypsomed's core competencies
  - Continue to invest in research & development and own technology platforms
  - Prepare for strategic initiative based on new proprietary technology

# Overview of Products and Applications

YPSOMED SELFCARE SOLUTIONS

Ypsomed's activities are organized in three business sectors:

| Self Injection Devices (OEM Business) | Pen Needles | Diabetes Care |
|---|---|---|
| ▪ **Development and manufacturing of custom-made self-injection devices for a wide range of pharmaceutical and biotech partners**<br>▪ **Marketed products include:**<br>  ▪ Disposable pens<br>  ▪ Reusable pens<br>  ▪ Semi-disposable pens<br>▪ **Product pipeline:**<br>  ▪ Auto-injectors<br>  ▪ Own technology platform | ▪ **Development and manufacturing of pen needles that fit all major brands of Self Injection Devices on the market (compatible with competitor pens)**<br>▪ **Patented click-on mechanism**<br>▪ **Needles allow for a convenient and user-friendly injection of the needed dose of medicine** | ▪ **Local access to customers and opinion leaders in various countries**<br>▪ **Direct distribution to customers in Germany**<br>  ▪ DiaExpert GmbH<br>  ▪ Mail order and Online shop |

# Overview of Pharma Partnerships

YPSOMED
SELFCARE SOLUTIONS

Insulin

sanofi aventis

hGH

Pfizer

Lilly

Genentech
IN BUSINESS FOR LIFE

interferon & EPO

Roche

# Overview of Pharma Partnerships

YPSOMED SELFCARE SOLUTIONS

r-hFSH serono

r-PTH NPS PHARMACEUTICALS

Symlin AMYLIN

... and other partners

# Exhibit 3

YPSOMED
SELFCARE SOLUTIONS

Ypsomed Holding AG
Brunnmattstrasse 6
PO Box
3401 Burgdorf / Switzerland
Tel. +41 34 424 41 11
Fax +41 34 424 41 55
www.ypsomed.com

# PRESS RELEASE

## Ypsomed reduces sales and profit forecasts and appoints new CEO

**Burgdorf, 14th September 2006, 7:30 a.m. – Ypsomed today has to issue an ad-hoc information due to lower than expected orders for insulin pen systems. Therefore sales and profitability for the business year 2006/07 will be lower than forecasted so far. At the same time Ypsomed announced the change of the CEO. The board of directors of Ypsomed has decided to nominate as of today Richard Fritschi, former president Europe & Australasia of Zimmer/Centerpulse, as the new CEO of the Ypsomed group.**

### Sales and profit will be lower than expected

Ypsomed today has to publish an ad-hoc information due to higher costs related to the temporary production stop and due to order volumes for insulin pens, which sanofi-aventis reduced compared to their forecasts at the beginning of the financial year 2006/07. The main reason stated by sanofi-aventis for this shortfall is a weaker demand, especially for the OptiClik® pen in the US market and delays in the launch of the OptiClik® pen in certain European countries. The temporary production stop of the OptiClik® pen resulted in higher additional costs in the first half year. Together with the lower than expected order forecast for the second half year this leads to significantly reduced sales in the core business and overall lower profitability for the business year 2006/07. Ypsomed will communicate more details at the presentation of the semi-annual results on 9th November 2006.

### Richard Fritschi appointed as new CEO of the Ypsomed group

Based on recent incidents the board of directors of Ypsomed took the decision to appoint a new CEO. As of today Richard Fritschi is the new CEO of the Ypsomed group. Willy Michel, Chairman of the board of directors, comments the decision as follows: "Richard Fritschi has over 15 years of medtech experience in executive positions and successfully managed in the past several take-overs, integration and change management projects. He brings to Ypsomed proven international leadership experience to effectively tackle the current challenges." Richard Fritschi was president Europe & Australasia for Zimmer and responsible for sales of CHF 1.3 billion and 2'000 employees until December 2005.

YPSOMED
SELFCARE SOLUTIONS

Richard Fritschi started his career at with Sulzer in 1991 as Vice President Finance & Controlling at Allo Pro AG. In 1998 he was promoted to General Manager Global Sales with the responsibility for all international sales of Sulzer Orthopedics. From 2001 on he served as President for Europe, Asia & Latin America within SulzerMedica/Centerpulse.

The board of directors expresses gratitude with Matthew Robin's achievements to successfully grow the injection business over the last 8 years and wishes him all the best for the future.

Further information is available from Daniel Kusio, Head of Investor & Public Relations at Ypsomed Holding AG. Tel. +41 34 424 41 43 or Tel +41 34 424 41 11. This press release and further documents are available in electronic form at www.ypsomed.com.

**Information about the telephone conference in English**

A telephone conference in English will held today on 14th September 2006 at 3:00pm (MEZ). Chairman Willy Michel, the new CEO Richard Fritschi and Head of Investor Relations Daniel Kusio will be available for questions. Please dial in about 5 minutes before the beginning of the conference call. A recording of the conference call will be available as audio-download on our web page from noon Friday, 15th September 2006. The dial-in numbers are as follows:

| | |
|---|---|
| Europe and ROW: | +41 (0) 91 610 56 00 |
| UK: | +44 (0) 207 107 0611 |
| USA: | +1 (1) 866 291 4166 |

# Exhibit 4

July 26, 2006

**VIA HAND DELIVERY**

Honorable Sidney Harris
Administrative Law Judge
U.S. International Trade Commission
500 E Street, S W, Room 317-H
Washington, DC 20436

Re: *Certain Insulin Delivery Devices, Including Cartridges Having Adaptor Tops, and Components Thereof*, Inv. No. 337-TA-572

Dear Judge Harris:

We write to inform you of an agreement between complainants and respondents to extend the deadlines in Ground Rules 2(f) and 2(g) for responding to interrogatories and requests for production, and Ground Rule 2(o) for serving privilege logs.

Specifically, on July 19 complainants served interrogatories and requests for production on the respondents; on July 20, respondents served interrogatories and requests for production on complainants. In a telephone conference on July 24, the parties agreed to several discovery-related matters, including extending the deadlines for responding to the pending discovery requests. The private parties agreed to exchange written responses by August 25, 2006. The private parties also agreed to confer later regarding a date for exchanging privilege logs.

Sincerely yours,

Delbert R. Terrill, Jr.
Joanna M. Ritcey-Donohue
Todd P. Taylor
White & Case LLP
701 Thirteenth Street, NW
Washington, D.C. 20005
Telephone: (202) 626-3600
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*Counsel for complainants Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc.*

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Telephone: (312) 913-0001
Facsimile: (312) 913-0002

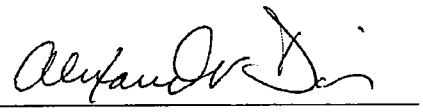
*Counsel for respondents Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis, and Aventis Pharmaceuticals, Inc.*

cc: Juan Cockburn, Esq.

**CERTIFICATE OF SERVICE**

I hereby certify that on July 31, 2006, a copy of the foregoing was served on the following as indicated:

| | |
|---|---|
| The Honorable Marilyn R. Abbott<br>Secretary to the Commission<br>U.S. International Trade Commission<br>500 E Street, S.W., Room 112-F<br>Washington, DC 20436 | **Electronic Filing** |
| The Honorable Sidney Harris<br>Administrative Law Judge<br>U.S. International Trade Commission<br>500 E Street, S.W., Room 317-H<br>Washington, DC 20436 | **One (1) Copy by Hand Delivery** |
| Juan Cockburn, Esq.<br>Office of Unfair Import Investigations<br>U.S. International Trade Commission<br>500 E Street, S.W., Room 401-Q<br>Washington, D.C. 20436 | **One (1) Copy by Hand Delivery** |
| **Counsel for Respondents Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis, and Aventis Pharmaceuticals, Inc.** | |
| Paul Berghoff<br>David M. Frischkorn<br>McDonnell, Boehnen, Hulbert & Berghoff LLP<br>300 South Wacker Drive<br>Chicago, IL 60606 | **One (1) Copy by First Class Mail and Electronic Mail** |
| Arthur Wineburg<br>Daniel E. Yonan<br>Akin Gump Strauss Hauer & Feld LLP<br>1333 New Hampshire Avenue, N.W.<br>Washington, DC 20036-1564 | **One (1) Copy by First Class Mail and Electronic Mail** |



Alexander Dennis

# Exhibit 5

WHITE & CASE

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Tel + 1 212 819 8200
Fax + 1 212 354 8113
www.whitecase.com

Direct Dial + (212) 819-8548 bwoodard@whitecase.com

September 20, 2006

VIA FACSIMILE

Alison J. Baldwin, Esq.
McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606

Nicole Keenan, Esq.
McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606

Re: Investigation No. 337-TA-572: In the Matter of Certain Insulin Delivery Devices, Including Cartridges Having Adaptor Tops, and Components Thereof

Dear Counsel:

I write in response to your letters dated September 18 and 19, 2006 addressed to Scott Weingaertner.

As an initial matter, your hollow attempt to cast Novo Nordisk as delaying discovery is transparent, unnecessary, and hypocritical given Aventis's failure to produce a single document until September 11. We were not informed until the September 8 teleconference with Ms. Baldwin that the "overwhelming majority" of Aventis's ITC document production would be identical to its Delaware production. Indeed, until then, Aventis failed to provide this information, or any information whatsoever concerning its non-existent document production, and did so only after being prompted by our calls and letter. Despite having produced on August 25 nearly 40,000 pages of relevant, technical and financial documents not produced in the Delaware action, Novo Nordisk received no documents from Aventis in this case until September 11 (other than those produced in response to the OUII requests), and the vast majority of Aventis's production was just received on September 15.

Moreover, if Aventis's ITC document production is in fact nothing more than a duplication of its Delaware production, as you seem to state, then as we advised Ms. Baldwin on September 8, Aventis's ITC production is woefully deficient. Given that we just received the

majority of Aventis's apparent 600,000-plus page ITC production on September 15, we have not yet had the opportunity to confirm that Aventis's ITC production is simply a copy of its Delaware production. As we pointed out to Ms. Baldwin, regardless of whether the OptiClik® device is at issue in both cases, Novo Nordisk's ITC document requests differ from its Delaware requests, and on that basis alone, so must Aventis's ITC production. Novo Nordisk's ITC requests are separate and tailored to the issues in the ITC action which involves, among other things, a different patent, different technology, different remedies, and other issues pertinent only to ITC proceedings. Conversely, given such differences between the ITC and Delaware cases, Aventis's Delaware production necessarily contains documents that are neither responsive to Novo Nordisk's ITC requests nor relevant to the issues in the ITC case.

After learning during the September 8 teleconference that Aventis's ITC production would be essentially identical to its Delaware production, we raised the above issues and concerns with Ms. Baldwin. Ms. Baldwin seemed to state that, as of September 8, Aventis had not searched for documents responsive to Novo Nordisk's ITC requests, and instead would be simply reproducing its Delaware production. Ms. Baldwin advised, in response to our request, that she would ascertain whether Aventis intended to search for and produce documents responsive to Novo Nordisk's ITC requests apart from Aventis's Delaware searches and production, and provide a reply by last week. We have heard nothing to date, and reiterate our request for such information.

We also requested that Aventis identify the specific documents in its Delaware production that are responsive to Novo Nordisk's ITC requests. Although Aventis offered to add ITC-specific Bates stamps to those documents produced in the Delaware action, based on a very preliminary review it appears that all or nearly all of the documents in the ITC production contain both sets of Bates stamps. We again request that you identify those documents that are responsive only to Novo Nordisk's ITC requests.

In addition, although Ms. Baldwin claims that Novo Nordisk has had access to Aventis's purported ITC document production for over one month, as noted above it was not until September 8, and only in response to Novo Nordisk's inquiries, that Aventis advised that most if not all of its ITC production would be the same as its Delaware production, and subsequently produced the majority of its documents late last week.

Moving on, Ms. Baldwin's letter of September 18 misrepresents and overcomplicates a simple and discrete issue and, apart from the above, the vast majority of the unfounded statements therein do not merit a response. We refer you to Mr. Weingaertner's letters of August 25 and September 13. Despite our numerous requests, Aventis still has failed to state whether it has undertaken the tremendous burden and expense (of potentially millions of dollars and hundreds if not thousands of personnel hours) of searching its limited accessibility electronic media for responsive materials. Given your recent representations that Aventis's ITC production is merely a duplicate of its Delaware production, however, Aventis clearly has not searched its limited accessibility electronic media in connection with the ITC proceeding because, as you are

well aware, the parties agreed that such searches are unnecessary (subject to certain conditions) in the Delaware action.

Despite the vast overbreadth of Aventis discovery requests, which includes 303 prior document requests and 41 more served just yesterday for an astounding total of **355**, Novo Nordisk has been and will continue to fully comply with its discovery obligations in the ITC proceeding, including the production of all relevant, responsive documents located after a reasonable and diligent search, including from electronic sources. Novo Nordisk has neither represented nor implied anything otherwise, and we expect the same from Aventis. We simply presented you a good faith proposal to reasonably limit discovery for both parties in order to alleviate the massive burdens and costs associated with searching limited accessibility electronic media, the exact same reasonable limitation agreed upon by both parties in the Delaware action. The only "unilateral" restriction is your seeming insistence that Novo Nordisk search its limited accessibility electronic media while Aventis need not do so. Novo Nordisk cannot and should not agree to such an unfair, unreasonable scenario.

We do not consider the limited accessibility electronic discovery issue to be at any "impasse," and there simply is no dispute to present to Judge Harris. We remain open and willing to discuss this mutual limitation on discovery – the exact limitation agreed upon in the Delaware case – that would alleviate the enormous burden for both parties of searching limited accessibility electronic data, as well as any other discovery issues. Your repeated threats to raise issues with the Court for which the parties have not even met and conferred, as required under Judge Harris's Ground Rules, are unnecessary and unproductive. In fact, Mr. Weingaertner's September 13 letter was a result of Ms. Baldwin's failure to return his calls and provide a response on September 11 as had been promised. The parties should negotiate outstanding disputes before needlessly bothering the Court, and we remain available to do so.

Last, we will respond to Aventis's purported concerns regarding Novo Nordisk's responses and objections to Aventis's first set of document requests, raised in one of Ms. Baldwin's September 5 letters, by the end of the week. In addition, Novo Nordisk is investigating the possible issue concerning its Japanese applications and endeavoring to collect the requested Novo Nordisk employee information. We will provide such information as soon as practically possible.

Sincerely,

Brendan G. Woodard

cc: Juan Cockburn, Esq.

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**Date:** September 20, 2006

**No. of Pages (including cover):** 4

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Contact Number: 312-935-2369

Nicole Keenan, Esq.
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312-935-2372

**cc:** Juan Cockburn
International Trade Commission
202-205-2158
202-205-2572

**From:** Brendan Woodard
**Reference No.:** 1123029-0011



Please see attached.

# Exhibit 6

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September 22, 2006

VIA FACSIMILE

Alison J. Baldwin, Esq.
McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606

Re: Investigation No. 337-TA-572: In the Matter of Certain Insulin Delivery Devices, Including Cartridges Having Adaptor Tops, and Components Thereof

Dear Alison:

This responds to your letter dated September 5, 2006, addressed to Scott Weingaertner, concerning Novo Nordisk's responses and objections to Aventis's first set of document requests.

As a general matter, Aventis's discovery requests, which currently total an astonishing 355 document requests, 36 interrogatories, and 84 requests for admission, are enormously overbroad, oppressive, and call for a overly broad range of material neither relevant to the issues in this case nor reasonably calculated to lead to the discovery of admissible evidence. Despite the overbroad and harassing nature of Aventis's requests, Novo Nordisk has undertaken to search for and provide responsive documents relevant to the claims and issues in this proceeding. Novo Nordisk will continue to do so, and expects Aventis to properly narrow the scope of its requests so as to avoid squandering both parties' time and resources in pursuing meaningless, irrelevant discovery.

With respect to your contentions regarding the identified General Objections, although Novo Nordisk stands by those objections, no documents have been withheld on any of those bases alone and, barring any unforeseen circumstances, none will be going forward.

Request No. 48

Novo Nordisk reiterates its objections to Request No. 48 which is, among other things, overbroad, vague and ambiguous, and seeks information neither relevant nor likely to lead to the discovery of admissible evidence. Subject to and without waiving its objections, however, Novo Nordisk states that it has produced or will produce relevant, non-privileged documents

concerning the invention claimed in the patent-in-suit to the extent that Novo Nordisk has custody and/or control over such documents and to the extent that such documents are located after a reasonable search.

Request Nos. 84-101

As noted above, Novo Nordisk is not withholding any documents on the basis alone that they are located outside of the United States. Novo Nordisk stands by and refers to its responses and objections to Request Nos. 84-101 and will produce or make available for inspection relevant materials as specified therein.

Request No. 105

Novo Nordisk reiterates and stands by its objections to Request No. 105 which, among other things, is vastly overbroad, seeks information neither relevant nor likely to lead to the discovery of admissible evidence, vague, ambiguous, and incomprehensible. You provide no clarification as to the types of documents sought by the Request, or how any such documents are relevant to the issues in this case other than to contend that they are. To the extent Complainants can even comprehend the Request, however, it is duplicative of some if not many of Aventis's other document requests in response to which Novo Nordisk has produced or will produce relevant, non-privileged documents located after a reasonable search.

Request Nos. 120, 192, 197-210, 213-221, 225-233, 235, 245-247, 249, 252-253, 256-257, 259

With respect to Aventis's definitions of "Medication Delivery Device" and "Related Product," Novo Nordisk's objections are entirely proper. "Medication Delivery Device," as defined by Aventis, is a limitless term that encompasses any device, or component of a device, that delivers medication by any means whatsoever. "Related Product" incorporates the term "Medication Delivery Device" and therefore is similarly flawed and unbound. These terms are so overbroad as to render the Requests incorporating them incomprehensible and not amenable to response, not to mention unduly burdensome and harassing, and seeking discovery of products entirely unrelated to the issues in this proceeding.

These Requests, many of them duplicative, seek a wide array of irrelevant documents. Novo Nordisk has complied and will continue to comply with its discovery obligations and has produced or will produce documents relevant to the claims and issues in this case. In fact, Novo Nordisk has agreed to produce documents responsive to some of these Requests. Novo Nordisk refers to and stands by its specific responses and objections to each of them.

Request No. 143

Novo Nordisk reiterates and stands by its objections to this Request. Aventis has access to Novo Nordisk press releases, and any drafts, to the extent any even exist, are simply not relevant to the issues in this case. Moreover, this Request seeks information protected by the attorney-client privilege and/or work product immunity.

Request Nos. 158, 250-251, 280-294, 300-301

Novo Nordisk reiterates its objections to each of these Requests which, again, seek a broad range of irrelevant material. You provide no explanation whatsoever as to how any of these categories of documents are relevant to the issues in this case, other than to contend that they are. Novo Nordisk stands by its objections to these Requests.

Again, Novo Nordisk will continue to comply with its discovery obligations by, among other things, producing relevant documents located after reasonable and diligent searches. Its investigation for and production of relevant documents responsive to Aventis's ITC requests is ongoing. As always, we stand ready to discuss any of your concerns.

We now return to Aventis's document production to date. Although we are still reviewing Aventis's some 630,000-page purported ITC production having received the majority of it just late last week, aside from a few documents, namely those produced in response to the OUII requests, it appears that Aventis's ITC production is in fact nothing more than a duplication of its Delaware production. Indeed, based on our early assessment, Aventis's Delaware production contains approximately 628,000 pages; its total ITC production contains approximately 629,500 pages. Leaving aside for the moment the questionable relevance and responsiveness of many of these documents (to either case), it appears that the only documents in the ITC production not containing both Delaware and ITC Bates numbers are the first 1371 pages (which were produced in response to the OUII requests), and the last approximately 500 pages. All of the documents in between appear to contain both sets of Bates numbers.

As pointed out in my September 20 letter, the issues, and Novo Nordisk's requests, differ between the two cases. Aventis's Delaware production necessarily contains documents that are neither responsive to Novo Nordisk's ITC requests nor relevant to any issue in the ITC case. For example, Aventis's Delaware production (and therefore its ITC production) contains hundreds and hundreds of patents and patent applications, comprising thousands and thousands of pages of material. The relevance and responsiveness of many of these documents to the '408 case is highly doubtful as it is, but they cannot possibly be relevant to the issues in the ITC proceeding which concerns an entirely different patent and invention, nor are they even responsive to Novo Nordisk's ITC document requests.

Novo Nordisk should not be required to endure the costly and time-consuming burden of wading through the hundreds of thousands of Aventis's Delaware documents to ascertain which are responsive to Novo Nordisk's ITC requests. That burden is Aventis's, which is obligated to search for and produce relevant, responsive material in the ITC proceeding. We therefore reiterate our requests that Aventis (1) confirm whether it has searched for, and will produce, documents responsive to Novo Nordisk's ITC requests apart from its Delaware searches and production (aside from the approximately 500 pages at the end of its ITC production), and (2) identify by Bates number the specific documents that are responsive to Novo Nordisk's ITC requests.

We also request, since for some unknown reason Aventis is using different Bates numbering for the two cases even though the documents are identical, that Aventis provide as soon as possible a "Text file" (a .txt document) that cross-references by Bates number every Aventis Delaware document with the corresponding ITC document. Novo Nordisk certainly should not be required to review the same 630,000-page production twice when Aventis can easily supply such information.

We remain open to discussing these or any other issues.

Sincerely,

BG. Woodard

Brendan G. Woodard

cc: Juan Cockburn, Esq.

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SERIAL BROADCAST REPORT (1)
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**Date:** September 22, 2006

**No. of Pages (including cover):** 5

**To:** Alison J. Baldwin
McDonnell Boehnen Hulbert & Berghoff LLP

**Fax Number:** 312-913-0002
Contact Number: 312-935-2369

**cc:** Juan Cockburn
International Trade Commission

202-205-2158
202-205-2572

**From:** Brendan Woodard

**Reference No.:** 1123029-0011



Please see attached.

# Exhibit 7

US005693027A

# United States Patent [19]

**Hansen et al.**

[11] **Patent Number: 5,693,027**

[45] **Date of Patent: Dec. 2, 1997**

[54] **ADAPTOR TOP**

[75] Inventors: **Ib Hansen**, Herlev; **Søren Mikkelsen**, Holte; **Frits Frydendal Bonnichsen**, Lynge, all of Denmark

[73] Assignee: **Novo Nordisk A/S**, Bagsvaerd, Denmark

[21] Appl. No.: **313,651**

[22] Filed: **Sep. 26, 1994**

**Related U.S. Application Data**

[63] Continuation of Ser. No. 53,503, Apr. 27, 1993, abandoned, which is a continuation of Ser. No. 768,684, filed as PCT/DK91/00282, Sep. 20, 1991, published as WO92/04926, Apr. 2, 1992, abandoned.

[30] **Foreign Application Priority Data**

Sep. 21, 1990 [DK] Denmark ..... 2282/90
May 16, 1991 [DK] Denmark ..... 926/91

[51] **Int. Cl.**[6] ..... **A61M 5/00**

[52] **U.S. Cl.** ..... **604/232**; 604/200; 604/51

[58] **Field of Search** ..... 604/232, 240–242, 604/200, 201, 905, 415, 181, 51; 215/324, DIG. 3

[56] **References Cited**

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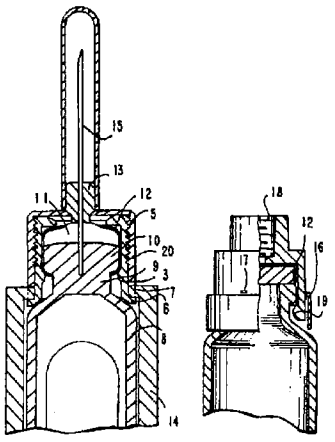
*Primary Examiner*—Michael Powell Buiz
*Assistant Examiner*—A. T. Nguyen
*Attorney, Agent, or Firm*—Steve T. Zelson, Esq.; James J. Harrington, Esq.

[57] **ABSTRACT**

A plastic top for adapting to a chosen syringe (14) a standard cartridge (8) of the kind having a neck (9) with a flange (10) and being closed by a rubber membrane (11) sealingly secured against the flange (10) by a metal cover (12) having its edge beaded behind the flange. This plastic top has a bore (2) for receiving the neck part (9) of the cartridge (8), which bore (2) has a diameter making it fit over the metal cover (12) and is provided with protrusions (3;9) gripping behind the edge of the metal cover (12) when the neck part (9) is inserted in the bore. The outer contour of the plastic top is adapted to the syringe type in which the cartridge is going to be used.

The plastic top is provided with a thread (5;18) coaxial with the bore to receive a needle hub (13) in a way making its needle (15) penetrate the membrane (11) of the cartridge (8) when the hub (13) is mounted on the thread (5) of the plastic top.

**19 Claims, 3 Drawing Sheets**



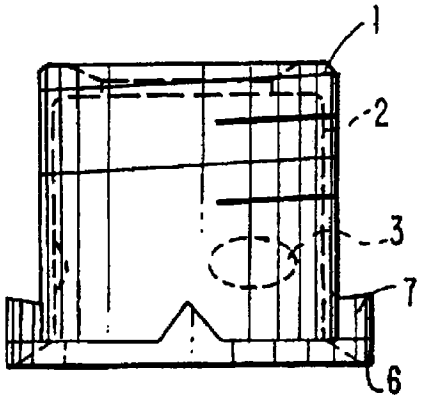



FIG. 1

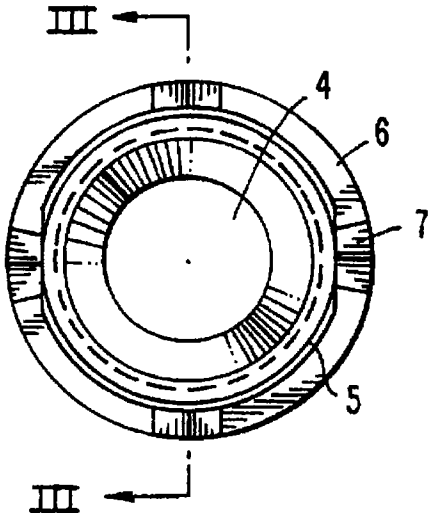



FIG. 2

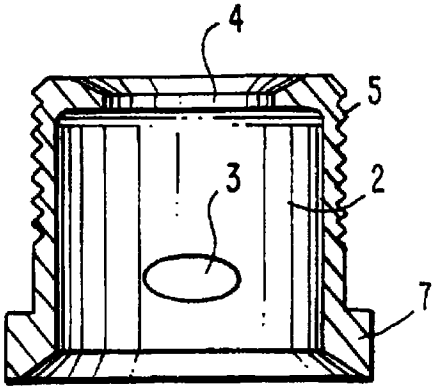



FIG. 3

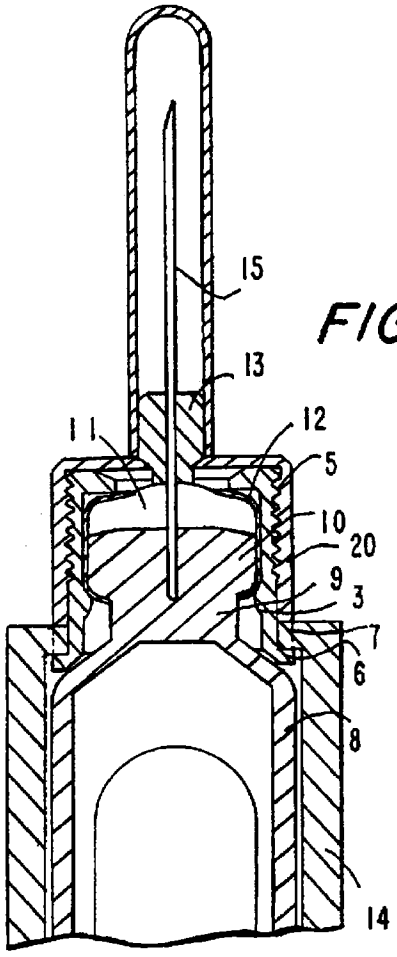



FIG. 4

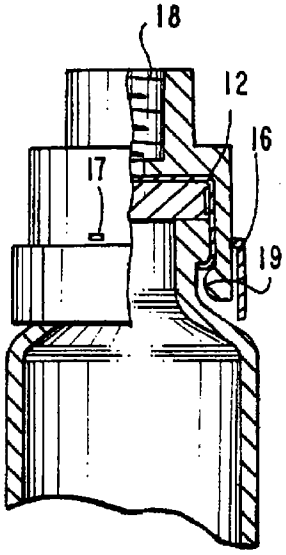



FIG. 5

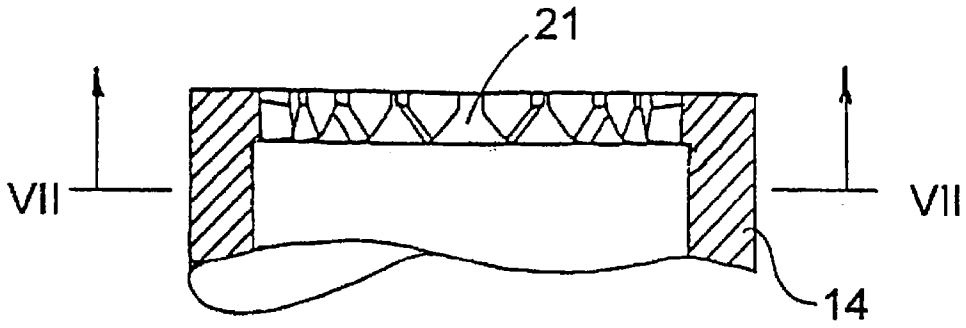



Fig. 6

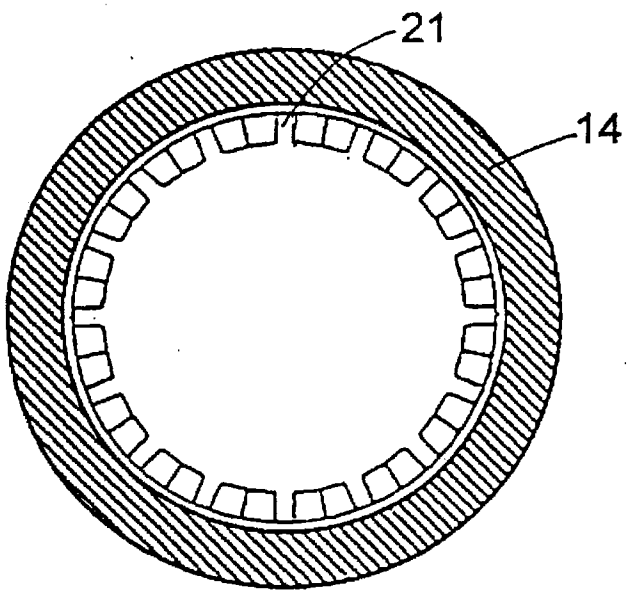



Fig. 7

# ADAPTOR TOP

This application is a continuation application of co-pending application Ser. No. 08/053,503, filed on Apr. 27, 1993, abandoned, which is a continuation of application Ser. No. 07/768,684 filed as PCT/DK91/00282 Sep. 20, 1991 published as WO92/04926 Apr. 2, 1992, the contents of which are incorporated herein by reference now abandoned.

The invention relates to ampules for pen syringes. Such ampoules are commonly shaped as a glass tube being at one end closed by a piston, which may be pressed into the tube to expel the content of the tube at the other end of the tube. This other end is formed as a bottle neck, the outer end of which is closed by a rubber membrane, which may be pierced by an injection needle through which the content is expelled.

## DESCRIPTION OF THE RELATED ART

In a standard cartridge the outer end of the bottleneck is provided with an external flange supporting the rubber membrane, and this membrane is sealingly secured over the opening of the neck against the flange by a metal cap having a central opening exposing the central part of the membrane over the opening of the neck, having side walls extending along the sides of the membrane and the flange, and having its end beaded to grip under the lower side of the flange.

As new types of pen syringes were developed the cartridges or at least the neck thereof was given different shapes to accommodate these types of syringes. The use of plastic closures instead of the standard metal cap has made it necessary to design the flanges for cooperation with such plastic tops which demand a greater accuracy of the glass flange if a reliable sealing shall be obtained. Consequently, the different insulin types each have to be marketed in different types of cartridges whereby the manufacturing and the stockpiling is made complicated.

## SUMMARY OF THE INVENTION

It is the object of the invention to provide a system of tops making a standard cartridge usable in an optional pen.

This is obtained by a plastic top which according to the invention has a bore for receiving the neck part of the cartridge, the bore having a diameter fitting over the metal cover, the inner wall of the bore being provided with protrusions for gripping behind the edge of the metal cover when the neck part is inserted into the bore, and the outer contour of the top being formed to adapt the chosen syringe type.

By using such a plastic top only one type of cartridges has to be manufactured as the adaption to a chosen type of syringe is made by the choice of plastic top. This means that the department filling the cartridges will not have to dispose of different filling machines or to rearrange existing machines to fill different types of cartridges with the same type of medicine. The mounting of the plastic top need not take place under sterile conditions as do the filling, and as the plastic top is of no importance to the sealing of the cartridges, the high accuracy demand may be reduced as the protrusions in the bore only have to secure the plastic top so that it cannot easily be removed, but do not have to prevent rotation or small axial movements of the plastic top on the neck part.

According to the invention the plastic top may be provided with a thread coaxial with the bore to receive a threaded needle hub carrying a double pointed needle, the thread of the top being provided so that when the needle hub is screwed onto the top mounted on a cartridge the one pointed end of the needle will penetrate the rubber membrane of the cartridge. This way the plastic top may serve the same purpose as do the known plastic closures.



The plastic top may be provided with means for keyed engagement with corresponding means in a syringe to keep it unrotable when mounted with a cartridge in the syringe. This is of importance when a needle should be screwed onto the top. In some types of syringes such keyed engagement between cartridge and syringe is further used to ensure that only a certain type of cartridge is used in the syringe.

According to the invention the top may be made from a coloured plastic in accordance with a colour code system for the content of the cartridges. Such a colour code system exists for insulin preparations revealing if a cartridge contains slow or quick acting insulin or a mixture thereof. Especially where the code top having an external thread is used the user is reminded of the type of medicine in the cartridge each time he has to screw a new needle onto the thread of the plastic top.

The plastic top may surround only the neck part of the cartridge or it may cover a bigger or smaller part of the cartridge and even form a part of the housing of a syringe, which may simplify the changing of cartridges.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in further details with reference to the drawing, wherein

FIG. 1 shows a front view of an embodiment of an adaptor top according to the invention,

FIG. 2 shows a plan view of the embodiment shown in FIG. 1,

FIG. 3 shows a sectional view along the line III—III in FIG. 2,

FIG. 4 shows a cylinder ampoule with an adaptor top as illustrated in FIGS. 1-3 mounted in a pen syringe,

FIG. 5 shows another embodiment of an adaptor top according to the invention.

FIG. 6 is a front, sectional view of the forward end of the pen syringe; and

FIG. 7 is a sectional view of the pen syringe, taken in the direction of the arrows VII—VII of FIG. 6.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

An adaptor top shown in FIG. 1 comprises a body 1 with a bore having a diameter slightly bigger than the diameter of the metal cap of a standard cylinder ampoule. The cylindric inner wall 2 of the bore is provided with protrusions 3 which may grip under the beaded lower edge of the metal cap of a standard ampoule, when the top is fitted with its bore over the closure of the ampoule. In the shown embodiment there are three protrusions with an angular spacing of 120°, but more protrusions or a single ring shaped protrusion may be used just as the scope of the invention is not deviated from by using two or one protrusion.

The protrusions 3 are given a height ensuring a good grip under the edge of the metal cap and the top is mounted by pressing the top with its bore over the metal cap making the protrusion pass the cap by the plastic material of the top being incidentally deformed. The protrusions 3 are placed in the bore of the body 1 in a position making them reach their gripping position under the edge of the metal cap before the

insertion of the ampoule neck part into the bore is stopped by the top of the closure abutting the bottom of the bore or the lower edge of the body **1** abutting the ampoule around its neck.

At the bottom of its bore **2** the adaptor top is provided with an opening **4** exposing part of the top of the metal cap with the rubber membrane laid bare. The adaptor top in the shown embodiment is intended for a needle in a hub having an internal thread and consequently it is provided with an outer thread **5** for receiving such a hub with its needle projecting through the opening **4**.

At its lower end the body **1** is provided with a flange **6** having triangular knobs **7** intended for cooperation with the syringe using an ampoule carrying this top. The engagement between the knobs **7** and corresponding recesses **21** (see FIGS. **4** and **6–7**) in the syringe keeps the top unrotable during screwing on the needle hub.

The outer cylindric contour of the body is shown with opposite flat cuts removing the thread **5** on opposite sides of the cylinder. Such cuts in the cylindric body shape may be made to provide a key for cooperation with a specific syringe, but is in the shown embodiment made for pure moulding related reasons.

FIG. **4** shows schematically the relevant parts of the syringe with an ampoule mounted using an adaptor top according to the invention. The parts of the adaptor top are given the reference numbers of similar parts in the embodiment shown in FIGS. **1–3**. A standard ampoule **8** has a neck **9** with a flange **10** against which a rubber membrane **11** is sealingly secured by a metal cap **12** beaded under the flange **10**. The bottom of the cup shaped cap **12** has an opening up through which part of the membrane **11** protrudes. The adaptor top is passed with its bore over the cap **12** and pressed down to make the protrusion **3** pass the metal cap and grip under the lower beaded edge of this cap. A needle hub **13** has a depending tubular skirt **20** having an internal thread to be screwed onto the outer thread **5** of the adaptor top with its needle **15** piercing the membrane **11** and projecting into the opening of the neck part of the ampoule. From the drawing it is noticed that the adaptor top is not the type having three protrusions 120° displaced, but has oppositely placed protrusions **3**.

The ampoule **8** with the adaptor top is inserted in a syringe housing **14** from the rear end thereof with the adaptor top projecting through an end wall of the syringe housing **14** and with the flange **6** of the adaptor top abutting this end wall. The end wall has recesses **21** to be engaged by the knobs **7** on the flange **6** and the top is this way held unrotably so that the needle hub may be screwed on the top. When screwed on the top the needle hub may be tightened to clamp the end wall of the housing **14** between the flange **6** and the lower edge of the skirt **20**. In another not shown embodiment the flange **6** may be omitted and the knobs **7** may be provided on the outer wall of the top and may be received in triangular recesses in the end wall of the syringe housing **14**.

In this way the ampoule is held in the syringe in a way making it easy to take out an empty ampoule by unscrewing the needle hub **7** as the ampoule is not wedged in the housing.

FIG. **5** shows another embodiment of an adaptor top mounted on a standard ampoule. Instead of discrete protrusions a ring-shaped protrusion **19** is running at the inner side of the bore. To make it possible to press this top over the metal cap **12** the lower edge carrying the protrusion has either to be very resilient or even to be slotted to enable a deformation allowing the protrusion to pass over the metal cap of the ampoule. Thereby the adaptor top may be too easy to remove unless as shown it is provided with an unresilient locking ring **16** which is kept in position by locking fingers **17**. This adaptor top is shown having in its opening an inner thread **18** for receiving a needle hub having an outer thread.

We claim:

**1**. A pen syringe assembly comprising:

(a) a housing having (i) an inner space and (ii) housing interlocking means which faces the inner space,

(b) an exchangeable standard cartridge, having a neck part with a flange, which is closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and

(c) an adaptor top having (i) a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge for receiving the metal cover of the cartridge therein, (ii) top interlocking means mating the housing interlocking means, and (iii) connecting means adapted to receive an exchangeable needle hub carrying a needle, wherein the adaptor top is mounted on the cartridge which has its neck part pressed into the bore, and wherein the cartridge with the adaptor top is accommodated in the inner space of the housing with the top interlocking means engaging the housing interlocking means.

**2**. A syringe assembly according to claim **1**, wherein the adaptor top is plastic and is provided with a thread coaxial with the bore for receiving a threaded needle hub.

**3**. A syringe assembly according to claim **2**, wherein the housing interlocking means and the adaptor top interlocking means prevent relative rotation between the syringe housing and the adaptor top.

**4**. A syringe assembly according to claim **3**, further comprising a needle assembly comprising a needle hub having a bore with an internal thread, wherein a portion of the adaptor top projects out of a forward end wall of the housing, wherein the adaptor top thread is an exterior thread on such portion, and wherein the needle hub screws over the portion of the adaptor top having the exterior thread to clamp the end wall between the needle hub and part of the adaptor top.

**5**. A syringe assembly according to claim **1**, wherein the bore of the adaptor top includes means for securing the metal cover against axial movement within the bore.

**6**. A syringe assembly according to claim **5**, wherein the means for securing the metal cover within the bore comprise means to engage the metal cover after the metal cover has been inserted a predetermined distance into the bore.

**7**. A syringe assembly according to claim **6**, wherein the means for securing the metal cover against axial movement within the bore comprises at least one protrusion in the bore that grips behind the beaded edge of the metal cover.

**8**. A syringe assembly according to claim **7**, wherein the means for securing the metal cover against axial movement within the bore includes a locking ring.

**9**. A syringe assembly according to claim **1**, wherein the adaptor top interlocking means are knobs at an end of the top, which knobs have triangular cross sections with the apex of the triangle directed towards an end wall of the housing, and wherein the housing interlocking means comprise corresponding triangular depressions in the housing.

**10**. A syringe assembly according to claim **1**, wherein the top is made from a colored plastic to carry information about the content of the cartridge.

**11**. A syringe assembly according to claim **1**, further including a needle assembly engaging the connecting means of the adaptor top.

12. A syringe assembly according to claim 1, wherein the housing interlocking means are located at an end wall of the housing.

13. In combination,

an exchangeable standard cartridge, having a neck part with a flange, which is closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and

an adaptor top having:

a first, axially extending portion having a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge, and an opening for exposing at least a part of the rubber membrane, wherein the metal cover is secured against axial movement within the bore;

a flange portion extending outwardly from the first portion, wherein the first, axially extending portion is adapted to pass through a forward opening in the housing of a syringe, and the flange portion is adapted to secure the adaptor top at a predetermined axial position relative to such syringe housing;

an interlocking member on the flange adapted to fit together with an interlocking means inside a syringe housing; and

connecting means adapted to receive an exchangeable needle hub carrying a needle.

14. The combination of claim 13, wherein the outside surface of the first portion is at least generally circular in cross-section, wherein the flange is an annular flange, and wherein the interlocking member is a projection.

15. The combination of claim 14, wherein the projection is a knob having a triangular cross-section, in which the apex of the triangle faces the direction in which the adaptor top is intended to be passed through a syringe housing.

16. A method of supplying a first medicament and a second medicament, comprising the steps of:

(a) providing the first medicament in a first, exchangeable standard cartridge, such standard cartridge being of the type which has a neck part with a flange closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and which is designed to be inserted into a syringe housing for dispensing the medicament through a needle;

(b) providing the second medicament in a second exchangeable standard cartridge;

(c) providing the first cartridge with a first adaptor top and providing the second cartridge with a second adaptor top, wherein each adaptor top has (i) a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge and means for securing the metal cover against axial movement within the bore, and (ii) top interlocking means adapted to mate with an interlocking means in a syringe housing, wherein the interlocking means of the first adaptor top differs from the interlocking means of the second adaptor top such that a syringe having housing interlocking means that mate with the interlocking means of the first adaptor top would not accept the interlocking means of the second adaptor top; wherein the first and second adaptor tops are mounted on the first and second cartridges, with their neck parts pressed into the bore, thereby to form first and second cartridge assemblies, respectively, and wherein each cartridge assembly includes a connecting means adapted to receive an exchangeable needle hub carrying a needle; and

(d) supply both the first and said second cartridge assemblies for marketing for administration to patients, wherein persons who utilize a syringe that accepts the adaptor top of said first cartridge assembly, for administering the first medicament, are unable to use the second cartridge assembly, and thereby administer the second medicament, using such syringe, thereby preventing an accidental administration of the second medicament.

17. A method according to claim 16, wherein the needle hub connecting means are provided on the respective adaptor tops, and further comprising the step of attaching an exchangeable needle hub on the connecting means.

18. A method of supplying a first medicament and a second medicament, comprising the steps of:

(a) providing the first medicament in a first, exchangeable standard cartridge, such standard cartridge being of the type having a neck part with a flange, which is closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and designed to be inserted into a syringe housing for dispensing the medicament through a needle;

(b) providing the second medicament in a second exchangeable standard cartridge;

(c) providing the first cartridge with a first adaptor top and providing the second cartridge with a second adaptor top, wherein each adaptor top has a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge and means for securing the metal cover against axial movement within the bore, wherein the first adaptor top has a color which differs from the second adaptor top so as to carry information as to the contents of each cartridge; wherein the respective adaptor top is mounted on a cartridge which has its neck part pressed into the bore, thereby forming first and second cartridge assemblies, respectively, and wherein each cartridge assembly includes a connecting means adapted to receive an exchangeable needle hub carrying a needle; and

(e) supplying both the first and said second cartridge assemblies for marketing for administration to patients, wherein persons intending to administer one type of medicament are able to utilize the color coding on the first and second adaptor types to distinguish between the type of medicament contained in the respective cartridges.

19. A method according to claim 18, wherein the needle hub connecting means are provided on the respective adaptor tops, and further comprising the step of attaching an exchangeable needle hub on the connecting means.

* * * * *

# Exhibit D

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# Exhibit E

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